STIC Search Report
EIC 3700

STIC Database Tracking Number: 138007

TO: Mike Peffley
Location: RND 7a71
Art Unit: 3739
Monday, November 22, 2004

Case Serial Number: 10/679245

From: Emory Damron
Location: EIC 3700
Randolph 8-A-34
Phone: 571-272-3520

Emory.Damron@uspto.gov

Search Notes

Dear Mike,

Please find below an inventor search in the bibliographic and full-text foreign patent files, as well as keyword searches in the patent and non-patent literature files, both bibliographic and full text.
References of potential pertinence have been tagged, but please review all the packets in case you like something I didn't.
Of those references which have been tagged, please note any manual highlighting which I've done within the document.
In addition to searching on Dialog, I also searched EPO/JPO/Derwent, Scirus/ScienceDirect, and Google Scholar.
There are a few decent references contained herein, but I'll let you determine how useful they may be to you.
Please contact me if I can refocus or expand any aspect of this case, and please take a moment to provide any feedback (on the form provided) so EIC 3700 may better serve your needs. Good Luck!
Sincerely,
Emory Damron
Technical Information Specialist
EIC 3700, US Patent & Trademark Office
Phone: (571) 272-3520/ Fax: (571) 273-0047
Emory.damron@uspto.gov

Solomon, Terrance

From: Unknown@Unknown.com
Sent: Tuesday, November 16, 2004 3:51 PM
To: STIC-EIC3700
Subject: Generic form response

ResponseHeader=Commercial Database Search Request

AccessDB#= 138007

LogNumber= ____________

Searcher= ____________

SearcherPhone= ____________

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MyDate=Tue Nov 16 15:50:43 EST 2004

submitto=STIC-EIC3700@uspto.gov

Name=Mike Peffley

Empno=71301

NOV 16 2004

Phone=(571) 272-4770

Artunit=3739

Office=Ran 7A71

Serialnum=10/679,245

Dialog = $ [illegible]
1026.92

PatClass=606/027   128/898

Earliest=March 27, 2003

Format1=paper

Searchtopic=A method for treating a patent foramen ovale ina heart, the method comprising: advancing a catheter device to a position in the heart and applying energy to tissues adjacent the patent foramen ovale with the catheter to substantially close teh patent foramen acutely.

The foramen ovale is basically a hole in the wall of the heart of a fetus. It exists to oxygenate the blood (i.e. bypass the lungs) since the lungs are yet working and the fetus relies on the mother. The foramen ovale typically closes during/shortly after birth and presents a problem if it doesn't sufficiently close. There are patents for physically sealing (i.e. suturing) but I have found no patents which utilize a catheter delivering energy for sealing the foramen ovale.

Comments=

send=SEND

STIC Search Results Feedback Form

EIC 3700

Questions about the scope or the results of the search? Contact ***the EIC searcher or contact***:

John Sims, EIC 3700 Team Leader
571-272-3507 RND 8 B35

Voluntary Results Feedback Form

- *I am an examiner in Workgroup:* 3739 *Example: 3730*
- *Relevant prior art* ***found****, search results used as follows:*
  - ☐ 102 rejection
  - ☐ 103 rejection
  - ☐ Cited as being of interest.
  - ☐ Helped examiner better understand the invention.
  - ☐ Helped examiner better understand the state of the art in their technology.

  Types of relevant prior art found:
  - ☐ Foreign Patent(s)
  - ☐ Non-Patent Literature
    (journal articles, conference proceedings, new product announcements etc.)
- *Relevant prior art* ***not found:***
  - ☐ Results verified the lack of relevant prior art (helped determine patentability).
  - ☐ Results were not useful in determining patentability or understanding the invention.

Comments:

Drop off or send completed forms to STIC/EIC3700 CP2 2C08

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LOUIS MORRIS
RND 8A20
PHONE: 571-272-3536

CINDY SDREWSKI
RND 8A20
PHONE: 571-272-3538

TECHNOLOGY CENTER 3700

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EIC3700

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TEAM LEADER, LIBRARIAN
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JEANNE HORRIGAN
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PHONE: 571-272-3529

EMORY DAMRON
SEARCHER
PHONE: 571-272-3520

WESSEN DEBELA
LIBRARY TECHNICIAN
PHONE: 571-272-3521

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Set     Items   Description
S1        389   AU=(MALECKI W? OR MALECKI, W? OR FRANCIS D? OR FRANCIS, D?
             OR HORNE K? OR HORNE, K? OR DEEM M? OR DEEM, M? OR GIFFORD H?
             OR GIFFORD, H? OR ALEJANDRO J? OR ALEJANDRO, J?)
S2        195    (WILLIAM OR BILL?)(2N)MALECKI OR (DAN OR DANIEL)(2N)FRANCIS
              OR (KEN OR KENNETH)(2N)HORNE OR MARK(2N)DEEM OR HANSON(2N)GI-
             FFORD OR JOSE(2N)ALEJANDRO
S3        695   PFO OR PATENT()FORAMEN? OR FORAMEN?()OVAL?
S4     308321   IC=A61B?
S5        127   S1:S2 AND S3:S4
S6         11   S5 AND S3
S7         11   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 347:JAPIO Nov 1976-2004/Jul(Updated 041102)
         (c) 2004 JPO & JAPIO
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200474
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File 348:EUROPEAN PATENTS 1978-2004/Nov W01
         (c) 2004 European Patent Office
File 349:PCT FULLTEXT 1979-2002/UB=20041118,UT=20041111
         (c) 2004 WIPO/Univentio
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INVENTOR-
AUTHOR
SEARCH

PatLit &
NonPatLit

BIBLIOGRAPHIC
&
FULL TEXT
FILES

[redacted]

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             OR HORNE K? OR HORNE, K? OR DEEM M? OR DEEM, M? OR GIFFORD H?
             OR GIFFORD, H? OR ALEJANDRO J? OR ALEJANDRO, J?)
S2        396   (WILLIAM OR BILL?)(2N)MALECKI OR (DAN OR DANIEL)(2N)FRANCIS
              OR (KEN OR KENNETH)(2N)HORNE OR MARK(2N)DEEM OR HANSON(2N)GI-
             FFORD OR JOSE(2N)ALEJANDRO
S3      11534   PFO OR PATENT()FORAMEN? OR FORAMEN?()OVAL?
S4          0   S1:S2 AND S3
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File   2:INSPEC 1969-2004/Nov W1
         (c) 2004 Institution of Electrical Engineers
File   5:Biosis Previews(R) 1969-2004/Nov W2
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File   6:NTIS 1964-2004/Nov W2
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File  34:SciSearch(R) Cited Ref Sci 1990-2004/Nov W2
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File  99:Wilson Appl. Sci & Tech Abs 1983-2004/Sep
         (c) 2004 The HW Wilson Co.
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         (c) format only 2004 The Dialog Corp.
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
         (c) 1998 Inst for Sci Info
File 481:DELPHES Eur Bus 95-2004/Nov W1
         (c) 2004 ACFCI & Chambre CommInd Paris
File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
         (c) 2002 The Gale Group
File   9:Business & Industry(R) Jul/1994-2004/Nov 18
         (c) 2004  The Gale Group
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         (c) 2004 F-D-C reports Inc.
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         (c) 2004 The HW Wilson Co.
File 129:PHIND(Archival) 1980-2004/Nov W1
         (c) 2004 Informa UK Ltd
File 130:PHIND(Daily & Current) 2004/Nov 18
         (c) 2004 Informa UK Ltd
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File 135:NewsRx Weekly Reports 1995-2004/Nov W2
         (c) 2004 NewsRx
File 148:Gale Group Trade & Industry DB 1976-2004/Nov 19
         (c)2004 The Gale Group
File 149:TGG Health&Wellness DB(SM) 1976-2004/Oct W4
         (c) 2004 The Gale Group
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         (c) 1999 The Gale Group
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         (c) 2004 Reed Business Information Ltd.
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         (c) 1999 AAAS
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         (c) 2004 ESPICOM Bus.Intell.
File 444:New England Journal of Med. 1985-2004/Nov W2
         (c) 2004 Mass. Med. Soc.
File 621:Gale Group New Prod.Annou.(R) 1985-2004/Nov 19
         (c) 2004 The Gale Group
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7/3,AU/1 (Item 1 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

016589096
WPI Acc No: 2004-747831/200473
Related WPI Acc No: 2004-689901; 2004-729153
XRPX Acc No: N04-590842
Method for treating patent foramen ovale **in heart, involves holding tissues adjacent to ovale together and applying energy to tissues for closing ovale acutely**
Patent Assignee: CIERRA INC (CIER-N)
Inventor: ALEGANDRO J; **DEEM M E ; FRANCIS D ; GIFFORD H S ; HORNE K ; MALECKI W**
Number of Countries: 108 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200486944	A2	20041014	WO 2004US9297	A	20040326	200473	B

Priority Applications (No Type Date): US 2004787532 A 20040225; US 2003458854 P 20030327; US 2003478035 P 20030611; US 2003490082 P 20030724
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200486944	A2	E	58	A61B-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
Designated States (Regional): AT BE BG BW CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PL PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW

7/3,AU/2 (Item 2 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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01166483
ENERGY BASED DEVICES AND METHODS FOR TREATMENT OF PATENT FORAMEN OVALE

DISPOSITIFS ET PROCEDES FONDES SUR L'APPLICATION D'UNE ENERGIE POUR LE TRAITEMENT DU FORAMEN OVALE **PERSISTANT**
Patent Applicant/Assignee:
CIERRA INC, 199 Jefferson Drive, Menlo Park, CA 94025, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
MALECKI William , 510 Clayton Street, San Francisco, CA 94117, US, US (Residence), US (Nationality), (Designated only for: US)
FRANCIS Dan , 1600 Villa Street, Apartment 392, Mountain View, CA 94941, US, US (Residence), US (Nationality), (Designated only for: US)
HORNE Kenneth , 926 Bautista Court, Palo Alto, CA 94303, US, US (Residence), US (Nationality), (Designated only for: US)
DEEM Mark E, 685 Sierra Avenue, Mountain View, CA 94041, US, US (Residence), US (Nationality), (Designated only for: US)
GIFFORD Hanson S III, 3180 Woodside Road, Woodside, CA 94062, US, US (Residence), US (Nationality), (Designated only for: US)
ALEGANDRO Jose, 617 Arcadia Terrace, Unit 101, Sunnyvale, CA 94087, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:

SMITH Scott M (et al) (agent), Townsend and Townsend and Crew LLP, Two
Embarcadero Center, 8th Floor, San Francisco, CA 94111-3834, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200486944 A2 20041014 (WO 0486944)
Application: WO 2004US9297 20040326 (PCT/WO US04009297)
Priority Application: US 2003458854 20030327; US 2003478035 20030611; US 2003490082 20030724; US 2004787532 20040225
Designated States:
(All protection types applied unless otherwise stated - for applications 2004+)
AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM
DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC
LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO
RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PL PT RO
SE SI SK TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) BW GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 14512

7/3,AU/3 (Item 3 from file: 350)
DIALOG(R)File 350:Derwent WPIX
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016570416
WPI Acc No: 2004-729153/200471
Related WPI Acc No: 2004-689901; 2004-747831
XRPX Acc No: N04-577532
Treatment method of patent foramen ovale **, involves advancing catheter having closure device at its distal end, into tissue of ovale to fix closure device in tissue**
Patent Assignee: CIERRA INC (CIER-N)
Inventor: **DEEM M E ; GIFFORD HANSON S ; HORNE K ; MALECKI W**
Number of Countries: 108 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200486951	A2	20041014	WO 2004US9533	A	20040326	200471	B

Priority Applications (No Type Date): US 2003665974 A 20030918; US 2003458854 P 20030327; US 2003478035 P 20030611; US 2003490082 P 20030724
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200486951	A2	E	46	A61B-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
Designated States (Regional): AT BE BG BW CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PL PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW

7/3,AU/4 (Item 4 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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01166589
METHODS AND APPARATUS FOR TREATMENT OF PATENT FORAMEN OVALE
METHODES ET APPAREIL POUR LE TRAITEMENT D'UN FORAMEN OVALE **PATENT**
Patent Applicant/Assignee:
CIERRA INC, 199 Jefferson Drive, Menlo Park, CA 94025-1114, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
DEEM Mark E, 685 Sierra Avenue, Mountain View, CA 94041, US, US (Residence), US (Nationality), (Designated only for: US)
GIFFORD Hanson S III, 3180 Woodside Road, Woodside, CA 94062, US, US (Residence), US (Nationality), (Designated only for: US)
MALECKI William , 510 Clayton Street, San Francisco, CA 94117, US, US (Residence), US (Nationality), (Designated only for: US)
HORNE Kenneth , 926 Bautista Court, Palo Alto, CA 94303, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
SMITH Scott M (et al) (agent), Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th Floor, San Francisco, CA 94111-3834, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200486951 A2 20041014 (WO 0486951)
Application: WO 2004US9533 20040326 (PCT/WO US04009533)
Priority Application: US 2003458854 20030327; US 2003478035 20030611; US 2003490082 20030724; US 2003665974 20030918
Designated States:
(All protection types applied unless otherwise stated - for applications 2004+)
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(AP) BW GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 8996

7/3,AU/5 (Item 5 from file: 350)
DIALOG(R)File 350:Derwent WPIX
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THIS APPLICATION

016531335
WPI Acc No: 2004-689901/200467
Related WPI Acc No: 2004-729153; 2004-747831
XRPX Acc No: N04-546626
Heart patent foramen ovale **treating method in newborn baby, involves applying laser energy to tissues adjacent to** patent foramen ovale **in heart, with catheter device to close** patent foramen ovale **acutely**
Patent Assignee: CIERRA INC (CIER-N)
Inventor: **ALEJANDRO J ; DEEM M E ; FRANCIS D ; GIFFORD H S ; HORNE K ; MALECKI W ;** ALEGANDRO J
Number of Countries: 108 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
US 20040193147	A1	20040930	US 2003458854	P	20030327	200467	B
			US 2003478035	P	20030611		

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                                      US 2003490082   P    20030724
                                      US 2003679245   A    20031002
WO 200486950   A2  20041014  WO 2004US9532   A    20040326  200467
WO 200487235   A2  20041014  WO 2004US9445   A    20040326  200467
Priority Applications (No Type Date): US 2003679245 A 20031002; US
  2003458854 P 20030327; US 2003478035 P 20030611; US 2003490082 P 20030724
Patent Details:
Patent No  Kind Lan Pg   Main IPC     Filing Notes
US 20040193147 A1    21 A61B-018/18    Provisional application US 2003458854

                                      Provisional application US 2003478035
                                      Provisional application US 2003490082
WO 200486950  A2 E     A61B-000/00
   Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ
   CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID
   IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ
   NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ
   UA UG US UZ VC VN YU ZA ZM ZW
   Designated States (Regional): AT BE BG BW CH CY CZ DE DK EA EE ES FI FR
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   TR TZ UG ZM ZW
WO 200487235  A2 E     A61M-000/00
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   UA UG US UZ VC VN YU ZA ZM ZW
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   TR TZ UG ZM ZW
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7/3,AU/6   (Item 6 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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" " WO VERSION OF THIS APPLICATION

01166588
ENERGY BASED DEVICES AND METHODS FOR TREATMENT OF PATENT FORAMEN OVALE

DISPOSITIFS A BASE D'ENERGIE ET METHODES POUR LE TRAITEMENT D'UN FORAMEN OVALE **PATENT**

Patent Applicant/Assignee:
  CIERRA INC, 199 Jefferson Drive, Menlo Park, CA 94025, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
  MALECKI William, 510 Clayton Street, San Francisco, CA 94117, US, US (Residence), US (Nationality), (Designated only for: US)
  FRANCIS Dan, 1600 Villa Street, Apartment 392, Mountain View, CA 94941, US, US (Residence), US (Nationality), (Designated only for: US)
  HORNE Kenneth, 926 Bautista Court, Palo Alto, CA 94303, US, US (Residence), US (Nationality), (Designated only for: US)
  DEEM Mark E, 685 Sierra Avenue, Mountain View, CA 94041, US, US (Residence), US (Nationality), (Designated only for: US)
  GIFFORD Hanson S III, 3180 Woodside Road, Woodside, CA 94062, US, US (Residence), US (Nationality), (Designated only for: US)
  ALEGANDRO Jose, 617 Arcadia Terrace, Unit 101, Sunnyvale, CA 94087, US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
  SMITH Scott M (et al) (agent), Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th Floor, San Francisco, CA 94111-3834, US,

Patent and Priority Information (Country, Number, Date):
Patent: WO 200486950 A2 20041014 (WO 0486950)
Application: WO 2004US9532 20040326 (PCT/WO US04009532)
Priority Application: US 2003458854 20030327; US 2003478035 20030611; US 2003490082 20030724; US 2003679245 20031002
Designated States:
(All protection types applied unless otherwise stated - for applications 2004+)
AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM
DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC
LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO
RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PL PT RO SE SI SK TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) BW GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 11615

7/3,AU/7 (Item 7 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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01166545
METHODS AND APPARATUS FOR TREATMENT OF PATENT FORAMEN OVALE
PROCEDES ET APPAREIL POUR LE TRAITEMENT DE FORAMEN OVALE PERMEABLE
Patent Applicant/Assignee:
CIERRA INC, 199 Jefferson Drive, Menlo Park, CA 94025-1114, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
GIFFORD III **Hanson** S, 3180 Woodside Road, Woodside, CA 94062, US, US (Residence), US (Nationality), (Designated only for: US)
DEEM Mark E , 685 Sierra Avenue, Mountain View, CA 94041 , US, US (Residence), US (Nationality), (Designated only for: US)
MALECKI William , 510 Clayton Street, San Francisco, CA 94117 , US, US (Residence), US (Nationality), (Designated only for: US
Legal Representative:
SMITH Scott M (et al) (agent), TOWNSEND AND TOWNSEND AND CREW LLP, Two Embarcadero Center, 8th Floor, San Francisco, CA 94111-3834, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200487235 A2 20041014 (WO 0487235)
Application: WO 2004US9445 20040326 (PCT/WO US04009445)
Priority Application: US 2003458854 20030327; US 2003478035 20030611; US 2003490082 20030724
Designated States:
(All protection types applied unless otherwise stated - for applications 2004+)
AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM
DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC
LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO
RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
(EP) AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PL PT RO SE SI SK TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) BW GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English

Fulltext Word Count: 14938

7/3,AU/8 (Item 8 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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00747985
METHODS AND APPARATUS FOR CARDIAC VALVE REPAIR
PROCEDE ET DISPOSITIF DE REPARATION DE VALVULE CARDIAQUE
Patent Applicant/Assignee:
EVALVE INC, 2761 Fair Oaks, Redwood City, CA 94063, US, US (Residence), US (Nationality)
Inventor(s):
DEEM Mark E , 216 B Palo Alto Avenue, Mountain View, CA 94041, US,
GIFFORD Hansen S III , 3180 Woodside Road, Woodside, CA 94062, US,
DIECK Martin S, 21105 Hazelbrook Drive, Cupertino, CA 95014, US,
FANN James I-Lin, 65 Prado Court, Portola Valley, CA 94028, US,
ST GOAR Frederick G, 2 Frederick Court, Menlo Park, CA 94025, US,
MARTIN Brian B, 315 Alder Road, Boulder Creek, CA 95006, US,
FAN Sylvia Wen-Chin, 3868 21st Street, Apt. 2, San Francisco, CA 94114, US,
GOLDFARB Eric A, 2822 Emerson Street, Palo Alto, CA 94306, US,
DELL Kent D, 1131 Grand Street, Redwood City, CA 94061, US,
POWELL Ferolyn T, 55 Caselli Avenue, San Francisco, CA 94114, US
Legal Representative:
HESLIN James M (et al) (agent), Townsend and Townsend and Crew LLP, 8th Floor, Two Embarcadero Center, San Francisco, CA 94111, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200060995 A2-A3 20001019 (WO 0060995)
Application: WO 2000US9290 20000407 (PCT/WO US0009290)
Priority Application: US 99128690 19990409
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB
GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA
MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA
UG UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
(AP) GH GM KE LS MW SD SL SZ TZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 30123

7/3,AU/9 (Item 9 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.

00379763
CLAMP ASSEMBLY AND METHOD OF USE
ENSEMBLE PINCE ET PROCEDE D'UTILISATION
Patent Applicant/Assignee:
HEARTPORT INC,
Inventor(s):
MALECKI William W ,
STERMAN Wesley D,

GIFFORD Hansen S III ,
MILLER Scott H
Patent and Priority Information (Country, Number, Date):
Patent: WO 9720506 A1 19970612
Application: WO 96US19258 19961203 (PCT/WO US9619258)
Priority Application: US 95567996 19951204; US 96595568 19960201
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AU CA JP AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE
Publication Language: English
Fulltext Word Count: 16046

7/3,AU/10 (Item 10 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.

00299768
THORACOSCOPIC DEVICES AND METHODS FOR ARRESTING THE HEART
DISPOSITIFS ET METHODES DE THORACOSCOPIE POUR ARRETER LE COEUR
Patent Applicant/Assignee:
STANFORD SURGICAL TECHNOLOGIES INC,
Inventor(s):
EVARD Philip C,
MACHOLD Timothy R,
Gifford Hanson S III ,
ROTH Alex T,
STERMAN Wesley D,
SIEGEL Lawrence C
Patent and Priority Information (Country, Number, Date):
Patent: WO 9517919 A1 19950706
Application: WO 94US14197 19941208 (PCT/WO US9414197)
Priority Application: US 93173899 19931227
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AU CA JP AT BE CH DE DK ES FR GB GR IE IT LU MC NL PT SE
Publication Language: English
Fulltext Word Count: 10470

7/3,AU/11 (Item 11 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.

00297564
DEVICES AND METHODS FOR INTRACARDIAC PROCEDURES
DISPOSITIFS ET PROCEDURES DE CHIRURGIE INTRA-CARDIAQUE
Patent Applicant/Assignee:
STANFORD SURGICAL TECHNOLOGIES INC,
Inventor(s):
STERMAN Wesley D,
GARRISON Michi E,
GIFFORD Hanson S III ,
STEVENS John H
Patent and Priority Information (Country, Number, Date):
Patent: WO 9515715 A1 19950615
Application: WO 94US13305 19941118 (PCT/WO US9413305)
Priority Application: US 93163241 19931206

Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AU CA JP AT BE CH DE DK ES FR GB GR IE IT LU MC NL PT SE
Publication Language: English
Fulltext Word Count: 16108

```
Set     Items   Description
S1         65   PFO OR PATENT()FORAMEN?()OVAL? OR FORAMEN?()OVAL?
S2        169   ASD OR ATRIAL?()SEPT?()DEFECT?
S3         94   (FETAL? OR FETUS? OR FOETAL? OR FOETUS? OR NEONAT? OR CONG-
             ENIT? OR INFANT? OR BABY?)(3N)(HEART? OR ATRIA? OR CORONAR? OR
              CARDI? OR INTRACARD?)(3N)(OPEN? OR DEFECT? OR HOLE?)
S4     677696   ENERG? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR LASER?
S5     145122   MICROWAV? OR ULTRASOUND? OR ULTRASON? OR ULTRA()(SOUND? OR
             SONIC? OR SONO?)
S6     546584   RESIST?()HEAT? OR CRYOGEN? OR TISSUE(3N)(FUSE? OR FUSI? OR
             WELD?) OR ELECTROD?
S7    1165391   CATHET? OR LUMEN? OR CANULA? OR CANNULA? OR CANULLA? OR CA-
             NNULLA? OR TUBE? OR PIPE? OR CONDUIT?
S8    1767310   SEAL? OR CLOSE? OR CLOSING? OR SHUT? OR TOGETHER
S9     531004   UNITE? OR UNITING? OR WELD? OR FUSE? OR FUSI? OR PLUG? OR -
             OCCLU?
S10   2065778   STAUNCH? OR HERMETIC? OR REPAIR? OR REPARAT? OR TREAT? OR -
             FIX OR FIXE?? OR FIXING?
S11    231998   MEND? OR CURE? OR CURING? OR CURATI? OR HEAL?
S12    883970   ACUTE? OR COMPLET? OR PERMANENT? OR IMMEDIAT? OR SYNCRON? -
             OR SYNCHRON? OR ENTIR?
S13    167103   IC=A61B?
S14        28   S1:S3 AND S4:S6
S15        22   S14 AND S7:S13
S16        28   S14:S15
S17        28   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200474
         (c) 2004  Thomson Derwent
?
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PAT LIT

BIBLIOG. FILES

SELECTED EDITED HITS

The inventors /
different
application

17/3,K/1
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

016589096 **Image available**
WPI Acc No: 2004-747831/200473
Related WPI Acc No: 2004-689901; 2004-729153
XRPX Acc No: N04-590842

Method for treating patent foramen ovale **in heart, involves holding tissues adjacent to ovale** together **and applying** energy **to tissues for** closing **ovale** acutely

Patent Assignee: CIERRA INC (CIER-N)
Inventor: ALEGANDRO J; DEEM M E; FRANCIS D; GIFFORD H S; HORNE K; MALECKI W
Number of Countries: 108 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200486944	A2	20041014	WO 2004US9297	A	20040326	200473	B

Priority Applications (No Type Date): US 2004787532 A 20040225; US 2003458854 P 20030327; US 2003478035 P 20030611; US 2003490082 P 20030724
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200486944	A2	E	58	A61B-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
Designated States (Regional): AT BE BG BW CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PL PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW

Method for treating patent foramen ovale **in heart, involves holding tissues adjacent to ovale** together **and applying** energy **to tissues for** closing **ovale** acutely

Abstract (Basic):

... A **catheter** device (90) is placed at a position in the heart for **treating** the ovale. The tissues such as septum secundum (SS) tissue and septum primum (SP) tissue adjacent to the ovale are held **together** . The **energy** such as **radio frequency** , **laser** , **ultrasound** , **resistive heat** and **microwave energies** is applied to the tissues for **closing** the ovale **acutely** .

... 1) **catheter** device; and...

...2) system for **treating patent foramen ovale** .

...

...For **treating patent foramen ovale** in heart using **catheter** device...

...Prevents stroke, migraine headache effectively by **closing** the ovale **acutely** .

...

...The figure shows a perspective view of the **catheter** device. (Drawing includes non-English language text...

... **catheter** device (90...

... **catheter** element (92

...Title Terms: **TREAT** ;

International Patent Class (Main): **A61B-000/00**

```
17/3,K/2
DIALOG(R)File 350:Derwent WPIX
(c) 2004  Thomson Derwent. All rts. reserv.

016531335    **Image available**
WPI Acc No: 2004-689901/200467
Related WPI Acc No: 2004-729153; 2004-747831
XRPX Acc No: N04-546626
  Heart  patent   foramen   ovale   treating  method in newborn baby,
  involves applying  laser   energy  to tissues adjacent to  patent
  foramen   ovale  in heart, with  catheter  device to  close   patent
  foramen   ovale   acutely
Patent Assignee: CIERRA INC (CIER-N)
Inventor: ALEJANDRO J; DEEM M E; FRANCIS D; GIFFORD H S; HORNE K; MALECKI W
  ; ALEGANDRO J
Number of Countries: 108  Number of Patents: 003
Patent Family:
Patent No      Kind   Date     Applicat No     Kind   Date      Week
US 20040193147  A1   20040930  US 2003458854    P   20030327  200467  B
                               US 2003478035    P   20030611
                               US 2003490082    P   20030724
                               US 2003679245    A   20031002
WO 200486950    A2   20041014  WO 2004US9532    A   20040326  200467
WO 200487235    A2   20041014  WO 2004US9445    A   20040326  200467
Priority Applications (No Type Date): US 2003679245 A 20031002; US
  2003458854 P 20030327; US 2003478035 P 20030611; US 2003490082 P 20030724
Patent Details:
Patent No  Kind Lan Pg   Main IPC    Filing Notes
US 20040193147 A1    21 A61B-018/18   Provisional application US 2003458854

                                     Provisional application US 2003478035
                                     Provisional application US 2003490082
WO 200486950  A2 E    A61B-000/00
   Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ
   CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID
   IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ
   NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ
   UA UG US UZ VC VN YU ZA ZM ZW
   Designated States (Regional): AT BE BG BW CH CY CZ DE DK EA EE ES FI FR
   GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PL PT RO SD SE SI SK SL SZ
   TR TZ UG ZM ZW
WO 200487235  A2 E    A61M-000/00
   Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ
   CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID
   IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ
   NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ
   UA UG US UZ VC VN YU ZA ZM ZW
   Designated States (Regional): AT BE BG BW CH CY CZ DE DK EA EE ES FI FR
   GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PL PT RO SD SE SI SK SL SZ
   TR TZ UG ZM ZW
  Heart  patent   foramen   ovale   treating  method in newborn baby,
  involves applying  laser   energy  to tissues adjacent to  patent
  foramen   ovale  in heart, with  catheter  device to  close   patent
  foramen   ovale   acutely

Abstract (Basic):
...        The  catheter  device (110) is advanced to a position in the
    heart, and  energy , e.g.  laser   energy  is applied to tissues
    adjacent to the  patent   foramen   ovale   ( PFO ) with the  catheter
    device to  close  the  patent   foramen   ovale   acutely .
```

This application

... An INDEPENDENT CLAIM is also included for heart **patent foramen ovale treating** apparatus...

...For **treatment** of heart **patent foramen ovale** in newborn babies...

...Enables to **seal** the **PFO immediately** after **treatment** . Leaves no foreign material in a patient's heart. Achieves cost reduction, thus rendering prophylactic **treatment** of **PFO** , such as for stroke prevention...

...The figure depicts the **catheter** passing through **PFO** .
...

... **PFO treatment** apparatus (100...

... **catheter** device (110...

... **energy** transmission portions (114
...Title Terms: **TREAT** ;
International Patent Class (Main): **A61B-000/00** ...

... **A61B-018/18**

17/3,K/14
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

012471289 **Image available**
WPI Acc No: 1999-277397/199923
XRPX Acc No: N99-207939

Radio frequency **balloon** catheter **for causing thermal trauma to** patent foramen ovale **and method of use - comprises sheath** catheter **deployably retaining** foramen ovale catheter **within it; positive and negative** electrodes **are located at** foramen ovale catheter **distal end, connected to** radio frequency energy **supply**

Patent Assignee: HEARTEN MEDICAL INC (HEAR-N)
Inventor: BROWN T R; NGUYEN H V; STAMBAUGH B D
Number of Countries: 083 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 9918871	A1	19990422	WO 98US21459	A	19981009	199923	B
AU 9910777	A	19990503	AU 9910777	A	19981009	199937	

Priority Applications (No Type Date): US 9761585 P 19971010
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9918871	A1	E	21	A61B-017/39	
AU 9910777	A			A61B-017/39	Based on patent WO 9918871

Designated States (National) (WO 9918871): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW
Designated States (Regional) (WO 9918871): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW

Radio frequency **balloon** catheter **for causing thermal trauma to** patent foramen ovale **and method of use...**

...**comprises sheath** catheter **deployably retaining** foramen ovale catheter **within it; positive and negative** electrodes **are located at** foramen ovale catheter **distal end, connected to** radio frequency energy **supply**

...Abstract (Basic): NOVELTY - The **radio frequency catheter** has a sheath **catheter** with a **foramen ovale catheter** deployably retained within it. Positive and negative **electrodes** are located at the end of the **foramen ovale catheter** connected to a **radio frequency energy** supply. A thermocouple monitors the temperature of the tissue that comes into contact with the **electrodes** . DETAILED DESCRIPTION - An INDEPENDENT CLAIM is also included for a method using the **catheter** .

...

...USE - Minimally invasive device for **closing** a **patent foramen ovale** .

...

...material behind. DESCRIPTION OF DRAWING(S) - The drawing shows a schematic plan view of the **radio frequency** balloon **catheter** and an axial cross sectional view of the distal end of the **catheter** . (11) Sheath **catheter** ; (16) **Foramen ovale** balloon **catheter** ; (26) Inflatable balloon; (31) **Radio frequency energy** supply; (41, 42) **Radio frequency electrodes** ; (43) Thermocouple

...Title Terms: **CATHETER** ;

International Patent Class (Main): **A61B-017/39**

17/3,K/15
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

012471288 **Image available**
WPI Acc No: 1999-277396/199923
XRPX Acc No: N99-207938

Radio frequency **balloon** catheter **for causing thermal trauma to** patent foramen ovale **and method of use - comprises sheath** catheter **retaining** foramen ovale **balloon** catheter **inflated by** radio frequency energy **conducting fluid, heated by** electrodes **within balloon, receiving** radio frequency energy

Patent Assignee: HEARTEN MEDICAL INC (HEAR-N)
Inventor: BROWN T R; NGUYEN H V; STAMBAUGH B D
Number of Countries: 083 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 9918870	A1	19990422	WO 98US21440	A	19981009	199923	B
AU 9910775	A	19990503	AU 9910775	A	19981009	199937	

Priority Applications (No Type Date): US 9762954 P 19971010
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9918870	A1	E	21	A61B-017/39	
AU 9910775	A			A61B-017/39	Based on patent WO 9918870

Designated States (National) [WO 9918870]: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW

Radio frequency **balloon** catheter **for causing thermal trauma to** patent foramen ovale **and method of use...**

...**comprises sheath** catheter **retaining** foramen ovale **balloon** catheter **inflated by** radio frequency energy **conducting fluid, heated by** electrodes **within balloon, receiving** radio frequency energy

...Abstract (Basic): NOVELTY - The **catheter** has a sheath (11) **catheter** retaining a **foramen ovale** balloon **catheter** (16) which has an inflatable balloon (26) disposed at its distal end. At least two **radio frequency electrodes** (41, 42) are attached to the **foramen ovale catheter** within the balloon. The balloon is inflated with a **radio frequency energy** conducting fluid, heated by a supply of **radio frequency energy** (31) attached to the **electrodes** , thermally traumatising adjacent tissue in use. A thermocouple (43) attached within the balloon monitors the...

...the balloon. DETAILED DESCRIPTION - An INDEPENDENT CLAIM is also included for a method using the **catheter** . TECHNOLOGY FOCUS - The balloon is able to resist deformation at high temperatures and is manufactured...

...USE - Minimally invasive device for **closing** a **patent foramen ovale** .

...

...material behind. DESCRIPTION OF DRAWING(S) - The drawing shows a schematic plan view of the **radio frequency** balloon **catheter** and an axial cross sectional view of the distal end of the **catheter** . (11) Sheath **catheter** ; (16) **Foramen ovale** balloon **catheter** ; (26) Inflatable balloon; (31) **Radio frequency energy** supply; (41, 42) **Radio frequency electrodes** ; (43) Thermocouple

...Title Terms: **CATHETER** ;

International Patent Class (Main): **A61B-017/39**

17/3,K/16
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

011128695
WPI Acc No: 1997-106619/199710
XRPX Acc No: N97-088218
Septic endomyocarditis treatment **for children with** congenital heart defects **- combines** treatment **with antibiotics and electrotherapy**
Patent Assignee: NOVOS BLOOD CIRCULATION PATHOLOGY INST (NSBL-R)
Inventor: CHERNOBROVINA L V; DOROZHKO G V; LITASOVA E E
Number of Countries: 001 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
RU 2062624	C1	19960627	SU 5059250	A	19920820	199710	B

Priority Applications (No Type Date): SU 5059250 A 19920820
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
RU 2062624	C1		2	A61N-001/30	

Septic endomyocarditis treatment **for children with** congenital heart defects - ...

...**combines** treatment **with antibiotics and electrotherapy**

...Abstract (Basic): The **treatment** consists of giving the patient a broad-spectrum antibiotic, e.g. by intra-muscular injection, followed 30 - 60 mins later by electro-therapy, using **electrodes** with an area of 35 sq cm to galvanise the projected zones of the heart...

...In a test using the above **treatment** the patient's temperature was brought down to a stable normal level after 7 sessions...
...Title Terms: **TREAT** ;

17/3,K/18
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.

010621055 **Image available**
WPI Acc No: 1996-118008/199613
XRPX Acc No: N96-098699

Device for closing **body anomaly such as vessel openings - has spherical or lenticular elements on free ends of wire shaped locking pieces which are attached to closure body by stitching**

Patent Assignee: CARDIA INC (CARD-N); SCHNEIDT B (SCHN-I)
Inventor: KOEHLER K P; SCHNEIDT B; SCHRAEDER R
Number of Countries: 018 Number of Patents: 005
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
EP 698373	A2	19960228	EP 95113341	A	19950824	199613	B
EP 698373	A3	19960612	EP 95113341	A	19950824	199632	
US 5702421	A	19971230	US 96585114	A	19960111	199807	
EP 698373	B1	20031105	EP 95113341	A	19950824	200377	
DE 59510820	G	20031211	DE 510820	A	19950824	200382	
			EP 95113341	A	19950824		

Priority Applications (No Type Date): DE 95U2000381 U 19950111; DE 94U13645 U 19940824
Patent Details:

```
Patent No  Kind Lan Pg   Main IPC     Filing Notes
EP 698373     A2 G  14 A61B-017/00
   Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI LU MC
   NL PT SE
EP 698373     A3       A61B-017/00
US 5702421    A     13 A61B-017/08
EP 698373     B1 G     A61B-017/12
   Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI NL PT
   SE
DE 59510820   G        A61B-017/12   Based on patent EP 698373
```

Device for closing **body anomaly such as vessel openings...**

...Abstract (Basic): are spherical or lenticular or have spherical or lenticular elements (40). The elements are polished **laser welded** pearls or polished titanium balls...

...The locking pieces are positionally **fixed** to the ends of the closure body by stitching. The body may be rotationally symmetrical...

...USE/ADVANTAGE - For use in **repairing** Ductus arteriosus, Atrium-septum defects, **Foramen oval** or Ventricle-septum defects. Allows for better holding of the body in the opening and...

...Abstract (Equivalent): are spherical or lenticular or have spherical or lenticular elements (40). The elements are polished **laser welded** pearls or polished titanium balls...

...The locking pieces are positionally **fixed** to the ends of the closure body by stitching. The body may be rotationally symmetrical...

...USE/ADVANTAGE - For use in **repairing** Ductus arteriosus, Atrium-septum defects, **Foramen oval** or Ventricle-septum defects. Allows for better holding of the body in the opening and...

...Title Terms: **CLOSE** ;
International Patent Class (Main): **A61B-017/00** ...

... A61B-017/08 ...

... A61B-017/12

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Set    Items   Description
S1     10484   PFO OR PATENT()FORAMEN?()OVAL? OR FORAMEN?()OVAL?
S2     26392   ASD OR ATRIAL?()SEPT?()DEFECT?
S3     55954   (FETAL? OR FETUS? OR FOETAL? OR FOETUS? OR NEONAT? OR CONG-
             ENIT? OR INFANT? OR BABY?)(3N)(HEART? OR ATRIA? OR CORONAR? OR
              CARDI? OR INTRACARD?)(3N)(OPEN? OR DEFECT? OR HOLE?)
S4   7545719   ENERG? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR LASER?
S5   1609222   MICROWAV? OR ULTRASOUND? OR ULTRASON? OR ULTRA()(SOUND? OR
             SONIC? OR SONO?)
S6   1182303   RESIST?()HEAT? OR CRYOGEN? OR TISSUE(3N)(FUSE? OR FUSI? OR
             WELD?) OR ELECTROD?
S7   3264784   CATHET? OR LUMEN? OR CANULA? OR CANNULA? OR CANULLA? OR CA-
             NNULLA? OR TUBE? OR PIPE? OR CONDUIT?
S8   4373874   SEAL? OR CLOSE? OR CLOSING? OR SHUT? OR TOGETHER
S9   4709519   UNITE? OR UNITING? OR WELD? OR FUSE? OR FUSI? OR PLUG? OR -
             OCCLU?
S10 13427333   STAUNCH? OR HERMETIC? OR REPAIR? OR REPARAT? OR TREAT? OR -
             FIX OR FIXE?? OR FIXING?
S11  6419655   MEND? OR CURE? OR CURING? OR CURATI? OR HEAL?
S12  8049251   ACUTE? OR COMPLET? OR PERMANENT? OR IMMEDIAT? OR SYNCRON? -
             OR SYNCHRON? OR ENTIR?
S13     9402   S1:S3 AND S4:S6
S14      802   S13 AND S8:S11(5N)S1:S3
S15      438   S13 AND S8:S11(5N)S4:S6
S16      201   S13 AND S8:S11(5N)S12
S17     1225   S14:S16
S18      454   S17 AND S7
S19      205   S18 AND S7(5N)(S4:S6 OR S8:S11)
S20      194   S19 AND PY<2004
S21      139   RD (unique items)
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         (c) 2002 The Gale Group
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Set     Items   Description
S1      10484   PFO OR PATENT()FORAMEN?()OVAL? OR FORAMEN?()OVAL?
S2      26392   ASD OR ATRIAL?()SEPT?()DEFECT?
S3      55954   (FETAL? OR FETUS? OR FOETAL? OR FOETUS? OR NEONAT? OR CONG-
             ENIT? OR INFANT? OR BABY?)(3N)(HEART? OR ATRIA? OR CORONAR? OR
              CARDI? OR INTRACARD?)(3N)(OPEN? OR DEFECT? OR HOLE?)
S4    7545719   ENERG? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR LASER?
S5    1609222   MICROWAV? OR ULTRASOUND? OR ULTRASON? OR ULTRA()(SOUND? OR
             SONIC? OR SONO?)
S6    1182303   RESIST?()HEAT? OR CRYOGEN? OR TISSUE(3N)(FUSE? OR FUSI? OR
             WELD?) OR ELECTROD?
S7    3264784   CATHET? OR LUMEN? OR CANULA? OR CANNULA? OR CANULLA? OR CA-
             NNULLA? OR TUBE? OR PIPE? OR CONDUIT?
S8    4373874   SEAL? OR CLOSE? OR CLOSING? OR SHUT? OR TOGETHER
S9    4709519   UNITE? OR UNITING? OR WELD? OR FUSE? OR FUSI? OR PLUG? OR -
             OCCLU?
S10  13427333   STAUNCH? OR HERMETIC? OR REPAIR? OR REPARAT? OR TREAT? OR -
             FIX OR FIXE?? OR FIXING?
S11   6419655   MEND? OR CURE? OR CURING? OR CURATI? OR HEAL?
S12   8049251   ACUTE? OR COMPLET? OR PERMANENT? OR IMMEDIAT? OR SYNCRON? -
             OR SYNCHRON? OR ENTIR?
S13      9402   S1:S3 AND S4:S6
S14       802   S13 AND S8:S11(5N)S1:S3
S15       438   S13 AND S8:S11(5N)S4:S6
S16       201   S13 AND S8:S11(5N)S12
S17      1225   S14:S16
S18       454   S17 AND S7
S19       205   S18 AND S7(5N)(S4:S6 OR S8:S11)
S20       194   S19 AND PY<2004
S21       139   RD (unique items)
S22        81   S18 AND S1
S23        59   S22 NOT S20
S24        46   RD (unique items)
? pause
?
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21/3,K/17 (Item 17 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)
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0009437653 BIOSIS NO.: 199497458938

Interventional pediatric cardiology: State of the art and future perspective

AUTHOR: Radtke Wolfgang A K
AUTHOR ADDRESS: S.C. Child. Heart Cent., Med. Univ. S.C., 171 Ashley Ave., Charleston, SC 29425-0680, USA**USA
JOURNAL: European Journal of Pediatrics 153 (8): p542-547 1994 **1994**
ISSN: 0340-6199
DOCUMENT TYPE: Article; Literature Review
RECORD TYPE: Abstract
LANGUAGE: English

1994

ABSTRACT: Interventional **catheter** therapy has drastically changed the practice of cardiac **catheterization** and the **treatment** of congenital heart disease. In some centers, interventions amount to 30% or more of all cardiac **catheterizations** . For some lesions, surgery has become obsolete. For valvular pulmonary stenosis, balloon dilatation is the...

...implantation is also being investigated for other lesions. Valvular pulmonary atresia can be opened by **catheter** technique. In the majority of patients over 6 kg, the patent ductus arteriosus is transvenously closed by implantation of the Rashkind **occluder** . Secundum or similar **atrial septal defects** and muscular ventricular septal defects can also be **closed** by **catheter** technique, but suitable specific **occluders** are not generally available at present. Therapeutic vascular **occlusions** , **radiofrequency** ablation of aberrant conduction pathways and arrhythmia foci are examples of other **catheter** interventions.

DESCRIPTORS:
MISCELLANEOUS TERMS: ... **CATHETER** INTERVENTION...

... **CATHETER** **OCCLUSION** ;

21/3,K/28 (Item 9 from file: 34)
DIALOG(R)File 34:SciSearch(R) Cited Ref Sci
(c) 2004 Inst for Sci Info. All rts. reserv.

08968724 Genuine Article#: 350MW No. References: 10

Title: Simultaneous transcatheter closure of an atrial septal defect **with an Amplatzer septal** occluder **and** radiofrequency **ablation of an accessory connection**

Author(s): Kannankeril PJ; Wax DF (REPRINT) ; Deal BJ; Johnsrude CL; Duffy CE
Corporate Source: CHILDRENS MEM HOSP,DIV CARDIOL, 2300 CHILDRENS PLAZA, BOX 21/CHICAGO//IL/60614 (REPRINT); CHILDRENS MEM HOSP,DIV CARDIOL/CHICAGO//IL/60614

Journal: CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS, **2000**, V51, N1 (SEP), P55-57
ISSN: 1522-1946 Publication date: 20000900
Publisher: WILEY-LISS, DIV JOHN WILEY & SONS INC, 605 THIRD AVE, NEW YORK, NY 10158-0012
Language: English Document Type: ARTICLE (ABSTRACT AVAILABLE)

Title: Simultaneous transcatheter closure of an atrial septal defect **with an Amplatzer septal** occluder **and** radiofrequency **ablation of an accessory connection**

, **2000**

Abstract: This report describes the first case of simultaneous transcatheter closure of an **atrial septal defect** and

radiofrequency ablation of an accessory connection. This was performed successfully on an 8-year-old boy...

...an attractive therapeutic alternative to surgical repair in this combination of relatively common cardiac conditions. **Cathet** . Cardiovasc. Intervent. 51:55-57, 2000. (C) 2000 Wiley-Liss, Inc.

...Identifiers-- **CATHETER** ABLATION; ARRHYTHMIAS; PATHWAY

21/3,K/58 (Item 1 from file: 94)

DIALOG(R)File 94:JICST-EPlus
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05535587 JICST ACCESSION NUMBER: 03A0560707 FILE SEGMENT: JICST-E

Left-sided radiofrequency catheter **ablation via** patent foramen ovale **in a patient with concealed WPW syndrome**

IIDA YOJI (1); NAKAZATO YUJI (1); SASAKI AKITOSHI (1); KAWANO YASUNOBU (1); NAKAZATO KAORU (1); TOKANO TAKASHI (1); YASUDA MASAYUKI (1); MINEDA YORIAKI (2); SUMIYOSHI MASATAKA (2)
(1) Juntendo Univ., School of Medicine, JPN; (2) Juntendo Univ., JPN

Juntendo Igaku(Juntendo Medical Journal), **2003** , VOL.49,NO.2, PAGE.222-225 , FIG.5, REF.6
JOURNAL NUMBER: G0715ABG ISSN NO: 0022-6769 CODEN: JUIZA
UNIVERSAL DECIMAL CLASSIFICATION: 616.12-08 616-007-07
LANGUAGE: Japanese COUNTRY OF PUBLICATION: Japan
DOCUMENT TYPE: Journal
ARTICLE TYPE: Original paper
MEDIA TYPE: Printed Publication

Left-sided radiofrequency catheter **ablation via** patent foramen ovale **in a patient with concealed WPW syndrome**
, 2003

ABSTRACT: We describe a case of concealed WPW syndrome which was successfully **treated** by **radiofrequency** catheter ablation via **patent foramen ovale**. A 52 year-old female was scheduled for **radiofrequency catheter** ablation due to paroxysmal supraventricular tachycardia. During electrophysiological study, a **patent foramen ovale** was disclosed. Ventricular pacing demonstrated retrograde atrial activation with earliest activation in the distal coronary...

...extrastimulation easily induced orthodromic AV reentry utilizing retrograde conduction over the accessory pathway. An ablation **catheter** was passed to the left atrium through the **patent foramen ovale**, and the left-sided accessory pathway was successfully ablated at its atrial attachment. An approach from a **patent foramen ovale** should be attempted for left-sided accessory pathways when it is detected on preoperative echocardiography...

...DESCRIPTORS: **catheter** ablation
IDENTIFIERS: **patent foramen ovale**
...BROADER DESCRIPTORS: heart **catheterization** ; ...

... **catheterization** ;

21/3,K/73 (Item 10 from file: 144)

DIALOG(R)File 144:Pascal

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12950636 PASCAL No.: 97-0225911

Percutaneous balloon catheter **closure of a** patent foramen ovale **in a patient with pulmonary disease, profound hypoxemia, and normal right heart pressures**

ALLAN J J; MARINELLI C; DELLSPERGER K C; WINNIFORD M D
The University of Iowa Hospitals and Clinics, Department of Internal Medicine, Cardiology Division, Iowa City, Iowa, United States

Journal: Clinical cardiology : (Mahwah, NJ), **1997**, 20 (3) 307-309
Language: English

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Percutaneous balloon catheter **closure of a** patent foramen ovale **in a patient with pulmonary disease, profound hypoxemia, and normal right heart pressures**

1997

Right-to-left intracardiac shunting across a **patent foramen ovale** (**PFO**) has been reported in patients with pulmonary embolism, right ventricular (RV) infarction, positive pressure ventilation...

... a patient with normal pulmonary pressures, severe hypoxemia, pulmonary disease, and intracardiac shunting across a **PFO** in whom it was difficult to determine how great a role intracardiac shunting was playing in his hypoxemia. To assess this, we performed percutaneous balloon **catheter occlusion** of the **PFO** , using transthoracic echocardiography with contrast to confirm closure of the **PFO** . Therapeutic balloon **occlusion** has been reported in severe hypoxemia due to shunting across a **PFO** in a patient with RV infarction. Our case is unique, however, in two respects. First...

... echocardiography with contrast was used before and after balloon inflation to confirm closure of the **PFO** . This technique helped to answer the important clinical question of whether surgical closure of the **PFO** in this patient with both lung disease and intracardiac shunting would significantly improve his oxygenation.

English Descriptors: Instrumental obliteration; Cuffed **tube** ; **Foramen ovale** ; Permeability; Hypoxemia; Echocardiography; Respiratory disease; Case study; Treatment; Human; Oxygen
Broad Descriptors: Instrumentation therapy; Sonography; Traitement instrumental; Exploration **ultrason** ; Tratamiento instrumental; Exploracion **ultrasonido**

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Set     Items   Description
S1        965   PFO OR PATENT()FORAMEN?()OVAL? OR FORAMEN?()OVAL?
S2       5215   ASD OR ATRIAL?()SEPT?()DEFECT?
S3       2334   (FETAL? OR FETUS? OR FOETAL? OR FOETUS? OR NEONAT? OR CONG-
             ENIT? OR INFANT? OR BABY?)(3N)(HEART? OR ATRIA? OR CORONAR? OR
              CARDI? OR INTRACARD?)(3N)(OPEN? OR DEFECT? OR HOLE?)
S4    3029236   ENERG? OR RADIOFREQUEN? OR RADIO()FREQUEN? OR RF OR LASER?
S5     263558   MICROWAV? OR ULTRASOUND? OR ULTRASON? OR ULTRA()(SOUND? OR
             SONIC? OR SONO?)
S6      83901   RESIST?()HEAT? OR CRYOGEN? OR TISSUE(3N)(FUSE? OR FUSI? OR
             WELD?) OR ELECTROD?
S7    1263772   CATHET? OR LUMEN? OR CANULA? OR CANNULA? OR CANULLA? OR CA-
             NNULLA? OR TUBE? OR PIPE? OR CONDUIT?
S8    6494986   SEAL? OR CLOSE? OR CLOSING? OR SHUT? OR TOGETHER
S9   18073605   UNITE? OR UNITING? OR WELD? OR FUSE? OR FUSI? OR PLUG? OR -
             OCCLU?
S10   3975166   STAUNCH? OR HERMETIC? OR REPAIR? OR REPARAT? OR TREAT? OR -
             FIX OR FIXE?? OR FIXING?
S11   4494048   MEND? OR CURE? OR CURING? OR CURATI? OR HEAL?
S12   7786277   ACUTE? OR COMPLET? OR PERMANENT? OR IMMEDIAT? OR SYNCRON? -
             OR SYNCHRON? OR ENTIR?
S13       797   S1:S3 AND S4:S6 AND S7
S14       182   S13 AND S7(5N)(S4:S6 OR S8:S11)
S15        88   S14 AND (S12 OR S1:S3)(5N)S8:S11
S16       209   S13 AND S1 AND S8:S11
S17       337   S14:S16
S18       315   S17 AND PY<2004
S19       246   RD (unique items)
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File   9:Business & Industry(R) Jul/1994-2004/Nov 18
         (c) 2004  The Gale Group
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19/3,K/50 (Item 1 from file: 135)
DIALOG(R)File 135:NewsRx Weekly Reports
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0000077113 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Minimally invasive procedure fixes **heart defect**
Medical Devices & Surgical Technology Week, February 23, 2003, p.73

DOCUMENT TYPE: Expanded Reporting LANGUAGE: English
RECORD TYPE: FULLTEXT
WORD COUNT: 1126

Minimally invasive procedure fixes **heart defect**

...TEXT: Eric's neurologist pursued other clues and ended up finding a heart defect called a **patent foramen ovale** , or **PFO** . A blood clot was believed to have slipped through the defect and out of the...
... Kar, MD, director of interventional cardiology research in the division of cardiology, was able to **repair** the defect using a minimally invasive nonsurgical approach to insert an innovative device, called CardioSEAL, to **close** the hole, saving Eric the physical stress and months of recovery of open-heart surgery...

...pumped out through the aorta to the arteries that feed the body.
The possibility of **PFO** arises because heart circulation is different before birth. The oxygen needs of the fetus are...

...the heart through the lungs. Instead, most of the blood flows through a hole (the **foramen ovale**) that exists between the two upper chambers of the heart, bypassing the right ventricle and...

...takes its first breath, pressure inside the vessels and the heart force a flap to **close** over the hole, rerouting the blood through the right ventricle and the lungs. This flap does not always **close** or **seal** tight enough to prevent some blood from passing between the upper chambers, at least occasionally...

...remain unnoticed even until late adulthood.
Kar said that in the past if an asymptomatic **PFO** happened by chance to be discovered, most surgeons chose to leave it untreated, especially because...

...bubbles of nitrogen that form in the blood during dives may pass through an untreated **PFO** .
The new technique enables physicians to reach the heart by inserting a **catheter** through a vein in the groin. The approach is similar to that used during routine cardiac **catheterization** . In the case of **PFO** closure, the **catheter** serves as a **conduit** for the delivery of the CardioSEAL, a double umbrella device made of polyester fabric mounted...

...Eric's procedure was performed in a cardiac cath lab. Using X-ray (angiography) and **ultrasound** imaging, Kar threaded the **catheter** from the groin through a vein into the heart. Because the slender **ultrasound** imaging **catheter** was also inserted through a vein to the heart, there was no need for an **ultrasound catheter** to be placed down the esophagus, a procedure that would have required general anesthesia.
Kar then attached the closure device to a thin cable and slid it through the **catheter** to the site of the defect. When it was properly positioned in the center of...

...of the defect. Heart wall tissue would grow around the device within a few months, **completely** and **permanently** **closing** the hole.

The procedure was accomplished in less than an hour with only mild sedation...

...Eric was able to see the closure device being deployed "like two umbrellas that spring **together** ," he said. If he had not already been hospitalized for the diagnostic procedures, the **treatment** most likely would have been performed on an outpatient basis. Instead, he was discharged the...

...with my parents the night I left," said Eric. "It really is incredible."

While a **PFO** is thought to be present in up to 12% of the normal population, as many...

...patients like Eric who have a stroke caused by an unknown source may have a **PFO** . This suggests that the mechanism of stroke in these patients is the escape, through the **PFO** , of a "paradoxical embolism" - a clot that forms in the veins but makes its way into the arterial circulation. Experts believe that stroke patients with a relatively large **PFO** are three times more likely than those without a **PFO** to suffer another stroke, even if placed on preventive medications.

The U.S. Food and...

...the device in early 2002 under the humanitarian device exemption for selected patients with a **PFO** who have a history of stroke from presumed paradoxical embolism passing through the **PFO** . The device has been in routine clinical use in Europe since 1996.

This article was...

SUBJECT HEADING: **Patent Foramen Ovale**

2003

19/3,K/52 (Item 3 from file: 135)
DIALOG(R)File 135:NewsRx Weekly Reports
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0000066726 (USE FORMAT 7 OR 9 FOR FULLTEXT)

Infant to go home after rare procedure offers alternative to open-heart surgery

Pain & Central Nervous System Week, September 16, 2002, p.9

DOCUMENT TYPE: Expanded Reporting LANGUAGE: English
RECORD TYPE: FULLTEXT
WORD COUNT: 317

...TEXT: after successfully undergoing a rare heart procedure that proved to be a successful alternative to **open - heart** surgery.

The **infant** was born with a form of pulmonary atresia, an extremely uncommon heart condition in which...

...is one of about 15-20 hospitals in the nation to use a specially designed **catheter** that can correct the valve without such invasive surgery.

... procedure reduced the baby's risks while still correcting the problem."

Doctors inserted the special **catheter** in a blood vessel in the child's leg and threaded it up into the heart. They then inserted a small wire up through the **catheter** and applied **radio frequency energy** to the valve. This essentially burned a small hole in the valve that was then ...

2002

19/9/52 **(Item 3 from file: 135)**
DIALOG(R)File 135:NewsRx Weekly Reports
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(Full Text Format of Previous Hit)

0000066726 (THIS IS THE FULLTEXT)

Infant to go home after rare procedure offers alternative to open-heart surgery

Pain & Central Nervous System Week, September 16, 2002, p.9

DOCUMENT TYPE: Expanded Reporting LANGUAGE: English
RECORD TYPE: FULLTEXT
AUDIENCE: Consumer
WORD COUNT: 317

TEXT: Doctors at Advocate Hope Children's Hospital announced that a 1-month-old infant will be going home after successfully undergoing a rare heart procedure that proved to be a successful alternative to **open - heart** surgery.

The **infant** was born with a form of pulmonary atresia, an extremely uncommon heart condition in which a key valve in the heart is fused shut, cutting off the blood flow from the heart to the lungs. Traditionally, open- heart surgery is the only means of treatment. However, Hope Children's Hospital is one of about 15-20 hospitals in the nation to use a specially designed **catheter** that can correct the valve without such invasive surgery.

Lead cardiologist Alexander Javois said open-heart surgery always increases certain risks, such as lung damage or stroke, but it creates a particularly delicate situation in a newborn. Pediatric cardiologists at Hope Children's Hospital said this alternative procedure poses far fewer risks to the patient.

"The benefit of this technology is that it increases the options we have in treating our patients," said Javois. "In this case, being able to use a much less invasive procedure reduced the baby's risks while still correcting the problem."

Doctors inserted the special **catheter** in a blood vessel in the child's leg and threaded it up into the heart. They then inserted a small wire up through the **catheter** and applied **radio frequency energy** to the valve. This essentially burned a small hole in the valve that was then stretched open with a balloon, creating an opening that allowed blood to flow through to the lungs. In this case, the infant had extra muscle tissue under the valve, so doctors later inserted a "shunt" or artificial channel in a minor surgical procedure to increase the flow of blood to the lungs.

This article was prepared by Pain & Central Nervous System Week editors from staff and other reports.

DESCRIPTORS: All News; Cardiology; Central Nervous System; Consumer News
SUBJECT HEADING: Cardiology
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19/3,K/233 (Item 43 from file: 444)
DIALOG(R)File 444:New England Journal of Med.
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00108762
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Catheter **Ablation Of Accessory Atrioventricular Pathways (Wolff-Parkinson-White Syndrome) By** Radiofrequency **Current (Original Articles)**

Jackman, Warren M.; Wang, Xunzhang; Friday, Karen J.; Roman, Carlos A. ; Moulton, Kriegh P.; Beckman, Karen J.; McClelland, James H.; Twidale, Nicholas; Hazlitt, H. Andrew; Prior, Michael I.; Margolis, P. David; Calame, James D.; Overholt, Edward D.; Lazzara, Ralph.
The New England Journal of Medicine
Jun 6, **1991** ; 324 (23),pp 1605-1611
LINE COUNT: 00358 WORD COUNT: 04953

Catheter **Ablation Of Accessory Atrioventricular Pathways (Wolff-Parkinson-White Syndrome) By** Radiofrequency **Current (Original Articles)**
1991 ;

Abstract

Background. Surgical or **catheter** ablation of accessory pathways by means of high- **energy** shocks serves as definitive therapy for patients with Wolff-Parkinson-White syndrome but has substantial associated morbidity and mortality. **Radiofrequency** current, an alternative **energy** source for ablation, produces smaller lesions without adverse effects remote from the site where current is delivered. We conducted this study to develop **catheter** techniques for delivering **radiofrequency** current to reduce morbidity and mortality associated with accessory-pathway ablation.

Methods. **Radiofrequency** current (mean power, 30.9 +/- 5.3 W) was applied through a **catheter electrode** positioned against the mitral or tricuspid annulus or a branch of the coronary sinus; when possible, delivery was guided by **catheter** recordings of accessory-pathway activation. Ablation was attempted in 166 patients with 177 accessory pathways...

...eliminated in 164 of 166 patients (99 percent) by a median of three applications of **radiofrequency** current. During a mean follow-up (+/- SD) of 8.0 +/- 5.4 months, preexcitation or...

...ablation in 75 patients verified the absence of accessory-pathway conduction in all. Complications of **radiofrequency** -current application occurred in three patients (1.8 percent): atrioventricular block (one patient), pericarditis (one), and cardiac tamponade (one) after **radiofrequency** current was applied in a small branch of the coronary sinus.

Conclusions. **Radiofrequency** current is highly effective in ablating accessory pathways, with low morbidity and no mortality. (N...

TEXT

...patients with the Wolff-Parkinson-White syndrome (Ref. 1-3). The successful introduction of percutaneous **catheter** ablation of the atrioventricular junction in 1982 (Ref. 4,5) stimulated interest in nonsurgical ablation of accessory atrioventricular pathways (Ref. 6-11). Initial approaches used, with moderate success, high- **energy** direct-current shocks delivered near the coronary-sinus ostium to ablate posteroseptal pathways (Ref. 12...

...surface of the tricuspid annulus to ablate right-free-wall pathways (Ref. 15-17). High- **energy** shocks were also applied, with very limited success, within the coronary sinus to ablate left...

...However, the use of high- **energy** shocks is associated with infrequent but serious complications, including cardiac perforation, cardiogenic shock, coronary-artery spasm, atrioventricular block, and late occurrence of ventricular fibrillation (Ref. 12-24). An alternative **energy** source, **radiofrequency** current, has been found to produce discrete lesions in animals without causing hemodynamic embarrassment, serious...

...stimulation (eliminating the need for general anesthesia) (Ref. 25). Further observations in animals suggested that **radiofrequency** current could safely produce lesions that would be successful in ablating accessory pathways (Ref. 26...

...and efficacy of this approach. The purpose of this study was to develop and evaluate **catheter** techniques for applying **radiofrequency** current to accessory pathways in different locations, as a means of increasing the safety of **catheter** ablation in patients with the Wolff-Parkinson-White syndrome...

...excluded for any technical reason, including the presence of multiple pathways; previous unsuccessful surgical or **catheter** ablation; accessory pathways anticipated to be in difficult locations; or previous inability to enter the...

...had undergone unsuccessful surgical ablation of the accessory pathway, and four others had undergone unsuccessful **catheter** ablation by high- **energy** direct-current shocks...

...The study protocol was approved by the Institutional Review Board of the University of Oklahoma **Health** Sciences Center. After providing written informed consent, each patient was studied in the post-absorptive...
...to 6 mg per hour). Oxygen saturation was monitored with a pulse oximeter. Five multipolar **electrode** **catheters** were inserted percutaneously into the right subclavian, right femoral, and left femoral veins and used...

...of the accessory pathway. Accessory pathways were localized by recording accessory-pathway activation potentials from **closely** spaced **electrodes** positioned near the sites of earliest ventricular activation during antegrade accessory-pathway conduction (sinus rhythm...

...tachycardia or ventricular pacing) (Ref. 36). To localize left-free-wall accessory pathways, an orthogonal **electrode** **catheter** was used in the coronary sinus (Ref. 37). To localize right-free-wall and septal accessory pathways, a **catheter** with a deflectable curve and **closely** spaced conventional **electrodes** was used to map the tricuspid annulus (Ref. 38...

...A **catheter** with a large-tip **electrode** (7 French; length, 4 mm; surface area, 27 mm(sup 2) Mansfield-Webster **Catheters** , Boston Scientific, Watertown, Mass.]) was used for ablation (Ref. 32). The **catheter** has a deflectable curve for maneuvering beneath the mitral or tricuspid leaflets. For the first 96 patients, **radiofrequency** current (continuous wave, 550 to 750 kHz) was generated by a conventional electrosurgical unit (Bicap...provided real-time monitoring of root-mean-square voltage, current, and impedance (Ref. 26,32).

Radiofrequency current was delivered at 45 to 60 V (usually 55 V) between the large-tip **catheter electrode** and a standard adhesive electrosurgical dispersive pad applied to the chest wall. **Energy** was usually applied during sinus rhythm in patients with preexcitation, and during ventricular pacing or...

...direction. When accessory-pathway conduction was lost within 10 to 15 seconds, the application of **energy** was maintained for 45 seconds but was terminated immediately in the event of an increase in impedance (resulting from formation of coagulum on the **electrode** (Ref. 39)) or displacement of the **catheter electrode** . Intravenous heparin in a bolus dose of 10,000 U and an infusion of 1000 U per hour was administered to all patients requiring a **catheter** in the left side of the heart.

Left-Free-Wall Accessory Atrioventricular Pathways

After localization of a left-free-wall accessory pathway by **electrodes** in the coronary sinus, coronary arteriography was performed to identify branches of the left circumflex coronary artery near the ablation site. The ablation **catheter** was then inserted through the right femoral arterial sheath and advanced retrogradely into the left ventricle. The large-tip **electrode** was positioned beneath the mitral leaflet, high against the mitral annulus at the site of the accessory pathway (Fig. 1A). The proximity of the **electrode** to the annulus and accessory pathway was confirmed by recording a large atrial potential (Ref. 26) and an accessory-pathway activation potential, respectively (Fig. 2A). *Figure 1.- **Catheter - Electrode** Positions for Accessory-Pathway Ablation (Radiographs in 30-Degree Right Anterior Oblique Projection). For ablation of a left anterolateral accessory pathway (Panel A), the ablation **catheter** (LV) was inserted through the right femoral artery and advanced into the left ventricle. The **catheter** tip was then curved, and the large-tip **electrode** was maneuvered beneath the mitral leaflet, high against the mitral annulus at the site of the accessory pathway. The small orthogonal **electrodes** on the coronary-sinus **catheter** (CS) were used for visual guidance of the ablation **catheter** to the correct region of the mitral annulus. For ablation of an anteroseptal accessory pathway (Panel B), the ablation **catheter** (Ab) was inserted through the right subclavian vein, advanced into the right ventricle, curved beneath the tricuspid leaflet, and positioned 2 mm anterior to the His-bundle **catheter** (HB). The other two **catheters** were located in the right atrial appendage (RAA) and right ventricular apex (RV) and were...

...a Posterior Left-Free-Wall Accessory Atrioventricular Pathway. Panel A shows recordings from the ablation **electrode** during sinus rhythm. From the top, the tracings are Lead II (and Lead III in...

...recorded from the right atrial appendage (RA), the His-bundle region (HB), and the ablation **electrode** (LV), which was positioned against the mitral annulus, beneath the mitral leaflet, as illustrated in...

...the delta wave (dotted vertical line). The tracings shown in Panel B were recorded when **radiofrequency** current was applied to the large-tip **electrode** on the left ventricular **catheter** at 48.3 V and 0.53 A (calculated power, 25.6 W). Accessory-pathway conduction ceased 3.9 seconds after the onset of the application of **radiofrequency** current (arrow), reflected by the lengthening of the PR interval and normalization of the QRS complex. Arterial pressure was unaffected by the application of **radiofrequency** current *. **FIGURE OMITTED...

...In the first eight patients, **radiofrequency** current was delivered between the large-tip **electrode** beneath the mitral annulus and a second large-tip **electrode** positioned in the coronary sinus, **close** to the accessory pathway. In the remaining 97 patients, **radiofrequency** current was delivered between the large-tip **electrode** beneath the mitral leaflet and a large skin **electrode** . If the large-tip **electrode** could not be adequately positioned beneath the mitral leaflet, it was positioned against the mitral annulus above the leaflet or a **catheter** was placed across the interatrial septum through a **patent foramen ovale** , or by a transseptal procedure.

Anteroseptal Accessory Atrioventricular Pathways

Accessory pathways were classified as anteroseptal...

...the accessory-pathway activation potential and the His-bundle potential were recorded by the same **close** bipolar **electrode** (Fig. 3A). To minimize the risk of atrioventricular block, **radiofrequency** current was delivered on the ventricular side of the tricuspid annulus. The ablation **catheter** was inserted through the right subclavian venous sheath and curved beneath the septal or anterior tricuspid leaflet (Fig. 1B). If this approach was unsuccessful, an ablation **catheter** was inserted through the right femoral venous sheath and placed parallel to the His-bundle **catheter** . *Figure 3.-Ablation of an Anteroseptal Accessory Atrioventricular Pathway. During sinus rhythm (Panel A), the bipolar **electrode** in the His-bundle region (HB, Fig. 1B) recorded activation potentials from both the accessory pathway and His bundle, indicating the **close** proximity of these two structures. During right atrial (RA) pacing at a cycle length of 450 msec (Panel B; S denotes pacing-stimulus artifact), the ablation **electrode** (Ab) was positioned beneath the tricuspid leaflet, high against the tricuspid annulus and slightly anterior...A) is smaller than on the His-bundle electrogram in Panel A, because the tip **electrode** approached the atrium from the ventricular side of the annulus. In Panel C, **radiofrequency** current (power, 39.4 W) was applied to the large-tip **electrode** on the ablation **catheter** (Ab) during atrial pacing at cycle length 450 msec. Accessory-pathway conduction ceased 1.7 seconds after the onset of the application of **radiofrequency** current (arrow) *. **FIGURE OMITTED**

Posteroseptal Accessory Atrioventricular Pathways

For posteroseptal accessory pathways, the ablation **catheter** was positioned in one of the following ways: (1) through the right femoral venous sheath, with the tip **electrode** placed against the tricuspid annulus or around the margin of the coronary-sinus ostium; (2) through the right femoral artery, with the tip **electrode** positioned against the mitral annulus, **close** to the septum, as in the approach used for left-free-wall pathways; or (3) through the right subclavian venous sheath, with the tip **electrode** positioned in a venous branch of the proximal coronary sinus (i.e., the middle cardiac vein).

Right-Free-Wall Accessory Atrioventricular Pathways

For right-free-wall accessory pathways, the ablation **catheter** was inserted through the right subclavian venous sheath and curved beneath the tricuspid leaflet, as in the approach to anteroseptal pathways. If this approach was unsuccessful, the ablation **electrode** was positioned above the tricuspid leaflet with a **catheter** inserted through either the right subclavian or right femoral venous sheath.

Multiple Accessory Atrioventricular Pathways

Two separate accessory pathways were considered to be present if sites where **radiofrequency** current affected accessory-pathway conduction were separated by more than 3 cm.

Post-Ablation Management

Thirty to 60 minutes after the final application of **radiofrequency** current, complete atrial and ventricular stimulation was repeated to verify the absence of accessory-pathway...

...procedure, which was successful in one. Successful ablation required a median of three applications of **radiofrequency** current at a mean power of 30.9 +/- 5.3 W delivered for a mean...

...7 +/- 23.7 seconds (Table 3). Accessory-pathway activation potentials were recorded from the ablation **electrode** at 91 percent of the sites where ablation was successful. The procedure lasted a mean...

...procedure was well tolerated; patients slept throughout the procedure under heavy sedation. The application of **radiofrequency** current had no effect on the heart rate or blood pressure and produced little or... atrioventricular nodal conduction at electrophysiologic study before ablation. Complete atrioventricular block followed the application of **radiofrequency** current to the posteroseptal tricuspid annulus near the posterior margin of the coronary-sinus ostium...

...the atrioventricular node. Hemopericardium and cardiac tamponade occurred in one patient after the application of **radiofrequency** **energy** in a small venous branch of the proximal coronary sinus. The intrapericardial blood was drained percutaneously, and the patient did not require surgery. Four other patients received **radiofrequency** current in a venous branch of the coronary sinus; pericarditis without effusion developed in one. There were no complications related to the application of **radiofrequency** current along the mitral or tricuspid annulus. Complications related to **cannulation** of the right femoral artery occurred in two patients: one patient had a small pseudoaneurysm of the right femoral artery, which was **repaired** under local anesthesia, and the other patient had a large femoral hematoma and required blood...

...Discussion

Although **radiofrequency** current produces smaller lesions than high- **energy** direct-current shocks, (Ref. 25) studies in animals have demonstrated that lesions potentially effective for accessory-pathway ablation can be produced when the ablation **electrode** is positioned firmly against the mitral or tricuspid annulus (Ref. 26,29). In the present study, designed to test this hypothesis, **radiofrequency** current eliminated ventricular preexcitation and atrioventricular reentrant tachycardia in 164 of 166 patients (99 percentThe principal reason for testing **radiofrequency** current was its potential to minimize the morbidity associated with ablation procedures. Even with experienced...

...of accessory-pathway conduction may be as high as 4 percent (Ref. 3,40). Although **catheter** ablation with high- **energy** direct-current shocks is better tolerated than surgery, it still carries an appreciable risk of...

...was no mortality, and complications occurred in only six patients (3.6 percent). Application of **radiofrequency** current to the endocardial surface of the mitral or tricuspid annulus did not result in...

...or cardiac tamponade occurred in two of five patients with posteroseptal accessory pathways in whom **radiofrequency** current was delivered through a small venous branch of the coronary sinus. This suggests that...

...The results of this study demonstrate that **catheter** delivery of **radiofrequency** current guided by direct recordings of accessory-pathway activation is highly effective in ablating accessory pathways, with no mortality and lower morbidity than surgical ablation or **catheter** ablation with high- **energy** shocks...

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S1        611   PFO OR PATENT()FORAMEN?()OVAL? OR FORAMEN?()OVAL?
S2       1411   ASD OR ATRIAL?()SEPT?()DEFECT?
S3        790   (FETAL? OR FETUS? OR FOETAL? OR FOETUS? OR NEONAT? OR CONG-
             ENIT? OR INFANT? OR BABY?)(3N)(HEART? OR ATRIA? OR CORONAR? OR
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S8      56629   IC=A61B?
S9       1253   S1:S3 AND S4:S6
S10      1027   S9 AND S7:S8
S11      1253   S9:S10
S12        41   S11 AND S4:S6(10N)S1:S3
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METHODS AND APPARATUS FOR TREATMENT OF PATENT FORAMEN OVALE
METHODES ET APPAREIL POUR LE TRAITEMENT D'UN FORAMEN OVALE PATENT

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Claims
Detailed Description
... nerves, etc. Also of interest are a number of patents by inventor Sinofsky, relating to **laser** suturing of biological materials (e.g., U.S.Patent Nos. 5,725, 522, 5,569...

...however, none of them show methods or apparatus suitable for positioning the tissues of the **PFO** for welding or for delivering the energy to the site to be welded.

3
[00121 Therefore, it would be advantageous to have improved methods and apparatus for treating a **PFO** . Ideally, such methods and apparatus would help seal the **PFO** while leaving only a harmless repair material, or possibly very little or no foreign material...

...and apparatus would be relatively simple to manufacture and use, thus rendering prophylactic treatment of **PFO** , such as for stroke prevention, a viable option.

Claim

1 . A method of treating a **patent** foramen **ovale** , the method comprising:

advancing a **catheter** having a proximal end, a distal end and a closure device near the distal end of the **catheter** into the tunnel of the **patent** foramen **ovale** ; and

4 fixing the closure device within the tunnel of the patent foranien ovale.

2...

...the closure device to cause adhesion between the closure device and tissue adjacent the patent **foramen** **ovale** .

3 A method as in claim 2, wherein bipolar **radiofrequency** energy is used to cause adhesion of the closure device to the tissue.

4 A method as in claim 2, wherein nionopolar **radiofrequency** energy is used to cause adhesion of the closure device to the tissue.

5 A method as in claim 2, wherein passing energy comprises applying **resistive** **heating** , **ultrasound** , **microwave** or **laser** energy.

6 A method as in claim 2, wherein passing energy into or through the...

...wherein passing energy into the closure device includes energizing a single conductive element of the **catheter** system.

8 A method as in claim 2, wherein passing energy into the closure device includes energizing a multiple conductive elements of the **catheter** system.

9 A method as in claim 1 or claim 6, wherein fixing the closure device within the **patent** foramen **ovale** tunnel includes activating tissue solder or adhesive to cause the adhesion.

10 A method as...

...I 11. A method as in claim 9, wherein tissue adhesive is infused into the **patent** foramen **ovale** tunnel while energy is being applied within the tunnel.

12 A method as in claim...

...skirt segment of the closure device to tissue surrounding a right atrial opening of the **patent** foramen **ovale** .

13 A method as in claim 1, wherein advancing the closure device into the **patent** foramen **ovale** includes providing lateral force to the **patent** foramen **ovale** .

14 A method as in claim 13, wherein advancing the closure device into the **patent** foramen **ovale** further includes providing dilatory force to the **patent** foramen **ovale** .

15 A method as in claim 1, wherein advancing the closure device into the **patent** foramen **ovale** includes engaging a positive stop to the periphery of the **patent** foramen **ovale** to control depth penetration of the treatment apparatus and/or closure device into the **patent** foramen **ovale** .

16 A method as in claim 1, claim 14 or claim 15, wherein advancing the closure device into the **patent** foramen **ovale** further includes allowing the closure device to expand within the **patent** foramen **ovale** prior to or during fixation.

17 A method as in claim 1, wherein advancing the closure device through the **patent** foramen **ovale** includes engaging a backstop member with a left atrial side of the **patent** foramen **ovale** to enhance fixation of the closure device.

18 A method of treating a **patent** foramen **ovale** , the method comprising:
advancing a **catheter** having a proximal end, a distal end and a closure device near the distal end of the **catheter** into the tunnel of the **patent** foramen **ovale** ; and applying energy to the closure device to cause adhesion between the closure device and tissue adjacent the **patent** foramen **ovale** , thereby fixing the closure device within the tunnel of the patent **foramen** **ovale** .

19 A method as in claim 18, wherein bipolar **radiofrequency** energy is used to cause adhesion of the closure device to the tissue.
20

20 A method as in claim 18, wherein monopolar **radiofrequency** energy is used to cause adhesion of the closure device to the tissue.
21 A...

...one of a tissue adhesive and a tissue solder.

24 A method of treating a **patent** foramen **ovale** , the method comprising:
advancing a **catheter** having a proximal end, a distal end and a closure device near the distal end of the **catheter** adjacent the tunnel of the **patent** foramen **ovale** ;
exposing at least one conducting element from the **catheter** ;
advancing the conducting element into the **patent** foramen **ovale** ; and applying energy to the closure device to cause adhesion between the closure device and tissue adjacent the **patent** foramen **ovale** , thereby fixing the closure device within the tunnel of the **patent** foramen **ovale** .

25 Apparatus for treating a **patent** foramen **ovale** , the apparatus comprising:
an elongate **catheter** having a proximal end and a distal end; and
at least one closure device releasably coupled with the **catheter** near the distal end, wherein the closure device may be fixedly deployed within the tunnel of the **patent** foramen **ovale** .
26 Apparatus as in claim 25, wherein no part of the at least one closure
...

...Apparatus as in claim 25, farther including at least one backstop member coupled with the **catheter** for engaging left atrial tissue adjacent the **patent** foramen **ovale** to enhance positioning of the patch within the tunnel.

30 Apparatus as in claim 25...

...as in claim 25, wherein the closure device expands to fill the tunnel of the **patent** foramen **ovale** .

37 Apparatus as in claim 25, wherein application of energy to the closure device causes the closure device to conform to geometry of the **patent** foramen **ovale** .

38 Apparatus as in claim 25, wherein application of energy to the closure device fixes the device to tissue of the **patent** foramen **ovale** .

39 Apparatus as in claim 25, wherein application of energy to the closure device ruptures...
...adhesive-filled compartments within the closure device to fix the device to tissue of the **patent** foramen **ovale** .

40 Apparatus as in claim 25, further comprising at least one energy transmission member coupled with the **catheter** body adjacent the distal. end for transmitting energy to the closure device.

41 Apparatus as...

...of radiofi-equency, resistive heating, ultrasound, microwave and laser energy.

42 Apparatus for,treating a **patent** foramen **ovale** , the apparatus comprising:
an elongate **catheter** body having a proximal end and a distal end; and at least one energy transmission member coupled with the **catheter** body adjacent the distal. end for transmitting energy to a closure device and tissue adjacent the **patent** foramen **ovale** to induce closure of the **patent** foramen **ovale** .

43 Apparatus as in claim 42, wherein the closure device is mounted on the at...

...Apparatus as in claim 42, wherein the energy transmission member transmits at least one of **radiofrequency** , **resistive heating** , **ultrasound** , **microwave** and **laser** energy.

46 Apparatus as in claim 42, wherein the at least one closure device comprises...

...Apparatus as in claim 42, further including at least one backstop member coupled with the **catheter** for engaging left atrial tissue adjacent the **patent** foramen **ovale** to enhance positioning of the patch within the tunnel.

49 Apparatus as in claim 42...

...patch within the tunnel.

50 Apparatus as in claim 42, wherein two or more **catheter** elements apply
lateral force to the **patent** foramen **ovale** prior to and/or during closure.

51 Apparatus as in claim 50, wherein the two or more **catheter** elements further apply dilatory forces to the **patent** foramen **ovale** prior to and/or during closure.

52 Apparatus as in claim 42, wherein transmission of...

...solder or tissue adhesive to cause fixation of the closure device to tissue of the **patent** foramen **ovale** .

53 Apparatus as in claim 42, wherein the at least one energy transmission member transmits...

16/3,K/16 (Item 16 from file: 349)
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"WO" VERSION OF THIS APPLICATION

01166588 **Image available**
ENERGY BASED DEVICES AND METHODS FOR TREATMENT OF PATENT FORAMEN OVALE
DISPOSITIFS A BASE D'ENERGIE ET METHODES POUR LE TRAITEMENT D'UN FORAMEN OVALE PATENT
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LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO
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Detailed Description
Claims

Detailed Description
... the energy transmission member comprises a guide member for advancing through the PFO, with the **catheter** device being slidably disposed over the guide member. Again, the guide member typically includes at least one expandable portion for expanding within the **PFO** to at least partially bring together the tissues adjacent the **PFO** , and in some embodiments the expandable member acts as the energy transmission member(s). In...

...00341 Apparatus of the invention may further include at least one sensor coupled with the **catheter** device for sensing an amount of energy delivered to the tissues by the at least...

...is a diagram of the fetal circulation;
[0037] FIG. 2 is a diagram of a **catheter** apparatus according to an embodiment of the present invention, having a conductive element and closure device, the **catheter** passing
through the inferior vena cava and right atrium and through the **PFO** ;
[0038] FIG. 3 is a perspective view of a **catheter** apparatus according to an embodiment of
the present invention;
[0039] FIG. 3A and 3B are cross-sectional views of the **catheter** apparatus in FIG. 3; [00401 FIG. 4 is a perspective view of a **catheter** apparatus according to another
embodiment of the present invention;

Claim

I 1. A method of treating a **patent** foramen **ovale** in a heart, the method comprising:

advancing a **catheter** device to a position in the heart for treating the **patent** foramen **ovale** ; and

. applying energy to tissues adjacent the **patent** foramen **ovale** with the **catheter** device to substantially close the **patent** foramen **ovale** acutely.

2 A method as in claim 1, further comprising bringing the tissues at le: ast partially together, using the **catheter** device.

3 A method as in claim 2, wherein the tissues are brought together beEbre ...

...comprises contacting the tissues with a tissue covering member adjacent a distal end of the **catheter** device.

8 A method as in claim 7, wherein contacting the tissues with the tissue ...

...as in claim 10, further comprising:
bringing the tissues at least partially together, using the **catheter** device; and holding the tissues together while applying the energy and while cooling the tissues.

12 A method as in claim 1, wherein advancing the **catheter** comprises positioning a distal end of the **catheter** in a right atrium of the heart.

13 A method as in claim 1, wherein advancing comprises advancing the **catheter** over a guide **catheter** extending into the **patent** foramen **ovale** .

14 A method as in claim 13, wherein the guide **catheter**0 extends through the **patent** foramen **ovale** into a left atrium of the heart.

15 A method as in claim 13, further comprising retracting a sheath portion of the guide **catheter** to expose an expanding member within the **patent** foramen **ovale** , the exposed expanding member bringing the tissues adjacent the **patent** foramen **ovale** at least partially together.

16 A method as in claim 15, wherein the exposed expanding member provides lateral force to the tissues adjacent the **patent** foramen **ovale** .

17 A method as in claim 16, wherein the exposed expanding member provides the lateral...

...the exposed expanding member, by contacting the tissues, aligns a cross-sectional center of the **catheter** device approximately with a cross-sectional center of the **patent** foramen **ovale** .

19 A method as in claim 15, further comprising:
contacting a left atrial surface of...

...of the expanding member; and
retracting the expanding member to bring the tissues adjacent the **patent**

foramen **ovale** together.
20 A method as in claim 19, ftirther including retracting the expanding member to a position within the guide **catheter** .
23

21 A method as in claim 20, further comprising removing the guide **catheter** through the **catheter** device after the expanding member is retracted within the guide **catheter** .

22 A method as in claim 21, wherein the guide **catheter** is removed before
applying the energy.

23 A method as in claim 1, wherein advancing comprises advancing the **catheter** over a guidewire extending through the **patent** foramen **ovale** , wherein the guidewire includes an expanding portion along its length for expanding within the **patent** foramen **ovale** .

24 A method as in claim 23, further comprising:
contacting a left atrial surface of...

...distal portion of the guidewire; and
retracting the guidewire to bring the tissues adjacent the **patent** foramen **ovale** together.

25 A method as in claim 1, wherein applying energy comprises applying at least one of **radiofrequency** energy, **cryogenic** energy, **resistive heat** energy, **ultrasound** energy, **microwave** energy and **laser** energy.

26 A method as in claim 25, wherein at least one of monopolar **radiofrequency** energy and bipolar **radiofrequency** energy is applied.

27 A method as in claim 25, wherein applying energy comprises energizing a single conductive member of the **catheter** device.

28 A method as in claim 25, wherein applying energy comprises energizing multiple conductive members of the **catheter** device.

29 A method as in claim 1, wherein applying energy comprises denaturing collagen in...

...a
sufficient amount of energy has been applied to the tissues to substantially close the **patent** foramen **ovale** acutely.
34 A method as in claim 33, further comprising discontinuing the application of energy...

...has been applied.

35 A method as in claim 1, further comprising directly visualizing the **patent** foramen **ovale** and the tissues using at least one visualization device coupled with the **catheter** device.

36 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
advancing a **catheter** device to a position in the heart for treating the **patent**

foramen **ovale** ; and
removing energy from tissues adjacent the **patent** foramen **ovale** with the
catheter device to substantially close the **patent** foramen **ovale** acutely.

37 A method as in claim 36, further comprising bringing the tissues at least partially together, using the **catheter** device.
38 A method as in claim 37, wherein the tissues are brought together before...

...comprises contacting the tissues with a tissue covering member adjacent a distal end of the **catheter** device.

42 A method as in claim 41, wherein contacting the tissues with the tissue...

...with the tissue covering member.

44 A method as in claim 36, wherein advancing the **catheter** comprises positioning a distal end of the **catheter** in a right atrium of the heart.

45 A method as in claim 36, wherein advancing comprises advancing the **catheter** over a guide **catheter** extending into the **patent** foramen **ovale** .

46 A method as in claim 45, wherein the guide **catheter** extends through the **patent** foramen **ovale** into a left atrium of the heart.
47 A method as in claim 45, further comprising retracting a sheath portion of the guide **catheter** to expose an expanding member within the **patent** foramen **ovale** , the exposed expanding member bringing the tissues adjacent the **patent** foramen **ovale** at least partially together.

48 A method as in claim 47, wherein the exposed expanding member provides lateral force to the tissues adjacent the **patent** foramen **ovale** .

49 A method as in claim 48, wherein the exposed expanding member provides the lateral...

...the exposed expanding member, by
contacting the tissues, aligns a cross-sectional center of the **catheter** device approximately with a cross-sectional center of the **patent** foramen **ovale** .

51 A method as in claim 47, further comprising:

contacting a left atrial surface...
...claim 5 1, further including retracting the expanding
member to a position within the guide **catheter** .

53 A method as in claim52, further comprising removing the guide **catheter** through the **catheter** device after the expanding member is retracted within the guide **catheter** .

54 A method as in claim 53, wherein the guide **catheter** is removed before
removing the energy.

55 A method as in claim 36, wherein advancing comprises advancing the **catheter** over a guidewire extending through the **patent** foramen **ovale** , wherein the guidewire includes an expanding portion along its length for expanding within the **patent** foramen **ovale** .

56 A method as in claim 55, further comprising:
contacting a left atrial surface of...

...distal portion of the guidewire; and
retracting the guidewire to bring the tissues adjacent the **patent** foramen **ovale** together.
57 A method as in claim 36, wherein removing energy comprises applying at least one **cryogenic** energy member to the tissues.

58 A method as in claim 36, further comprising monitoring...

...a
sufficient amount of energy has been removed from the tissues to substantially close the **patent** foramen **ovale** acutely.

62 A method as in claim 61, further comprising discontinuing the application of energy...

...has been removed.

63 A method as in claim 36, further comprising directly visualizing the **patent** foramen **ovale** and the tissues using at least one visualization device coupled with the **catheter** device.

64 Apparatus for treating a **patent** foramen **ovale** in a heart, the apparatus
comprising:
a **catheter** device having a proximal end and a distal end; and
at least one energy transmission...

...adjacent the distal end for applying energy to or removing energy from tissues adjacent the **patent** foramen **ovale** to substantially close the **patent** foramen **ovale** acutely.

65 Apparatus as in claim 64, further comprising at least one tissue apposition member...

...covering member.

69 Apparatus as in claim 68, wherein the tissue covering member covers the **patent** foramen **ovale** to allow blood pressure in a left atrium of the heart to bring the tissues...

...68, further comprising a flexible isolation
portion disposed between the tissue covering member and the **catheter** device to prevent unwanted movement of the tissue covering member during use.

73 Apparatus as...
...74 Apparatus as in claim 64, further comprising a guide member for advancing through the **patent** foramen **ovale** , wherein the **catheter** device is slidably disposed over the guide member.

75 Apparatus as in claim 74, wherein the guide member comprises:

a guide **catheter** ; and
at least one expandable member disposed within the guide **catheter** , whereiin the guide **catheter** is retractable to expose the expandable member to allow it to expand within the **patent** foramen **ovale** .

76 Apparatus as in claim 75, wherein the expandable member comprises at least two members that expand apart to provide lateral force to the tissues adjacent the **patent** foramen **ovale** .

77 A method as in claim 76, wherein the exposed expanding member provides the lateral...

...at least
one tip for contacting a left atrial surface of the tissues adjacent the **patent** foramen **ovale** .

82 Apparatus as in claim 8 1, wherein the at least one tip is conformable ...

...in claim 84, wherein the guide member comprises an
expandable member for expanding within the **PFO** , and wherein the expandable member comprises at least one **radiofrequency** energy transmission member.

86 Apparatus as in claim 64, wherein the at least one energy transmission member transmits at least one of **radiofrequency** energy, **cryogenic** energy, **resistive heat** energy, **ultrasound** energy, **microwave** energy and **laser** energy.

87 Apparatus as in claim 86, wherein the at least one energy transmission member comprises at least one monopolar **radiofrequency** transmission member.

88 Apparatus as in claim 86, wherein the at least one energy transmission member comprises at least two bipolar **radiofrequency** transmission members.

89 Apparatus as in claim 86, wherein the at least one energy transmission member comprises at least one curved **radiofrequency** transmission member.

90 Apparatus as in claim 86, wherein the at least one energy transmission ...

...the at least one energy transmission member comprises a guide member for advancing through the **patent** foramen **ovale** .
30

92 Apparatus as in claim 91, wherein the guide member includes at least one expandable portion for expanding within the **patent** foramen **ovale** to at least partially bring together the tissues adjacent the **patent** foramen **ovale** .

93 Apparatus as in claim 64, further comprising at least one sensor coupled with the **catheter** device for sensing an amount of energy delivered to the tissues by the at least...

...of energy.

96 Apparatus as in claim 64, further comprising a microprocessor coupled

with the **catheter** device for sensing and controlling energy transmission by the energy transmission member.

16/3,K/17 **(Item** 17 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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related to this application

01166545 **Image available**
METHODS AND APPARATUS FOR TREATMENT OF PATENT FORAMEN OVALE
PROCEDES ET APPAREIL POUR LE TRAITEMENT DE FORAMEN OVALE PERMEABLE
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LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO
RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
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Claims

Claim
... at least partially through the patent foramen ovale
to induce closure of the patent foramen **ovale** ,
wherein a portion of the closure device disposed within the **patent**
foramen **ovale** applies lateral force against tissues at opposite sides
of the **patent** foramen **ovale** to bring tissue between the sides
together.

36 A method as in claim 35, further comprising transmitting energy
comprising at least one of **laser** energy, **radio** **frequency** energy,
ultrasound energy and
31
microwave energy from the **catheter** to secure the closure device to
the tissues adjacent the **patent** foramen **ovale** .

37 A method as in claim 36, farther comprising delivering a tissue solder

material which...

...closure device to the tissue.

38 A method as in claim 35, farther comprising transmitting **cryogenic** energy or removing energy via cooling from the **catheter** to secure the closure device to the tissues adjacent the **patent** foramen **ovale** .

39 A method as in claim 36, 37 or 38, wherein transmitting energy causes the tissue adjacent the **patent** foramen **ovale** to weld together to close the **patent** foramen **ovale** .

40 A method as in claim 35, further comprising allowing the closure device to collapse...

...A method as in claims 35, farther comprising inflating an expandable balloon coupled with the **catheter** device near the distal. end to deploy the closure device within the **patent** foramen **ovale** .

43 A method as in claim 35, wherein delivering the closure device comprises:
releasing a left atrial portion of the closure device from the **catheter** device such that it contacts tissue adjacent the **patent** foramen **ovale** from within in a left atrium of
the heart; and
releasing a right atrial portion of the closure device from the **catheter** device such that it contacts tissue adjacent the **patent** foramen **ovale** from within in a left atrium of
the heart,
wherein a bridging portion of the closure device extends through the **patent** foramen **ovale** between the left atrial portion and the right atrial portion and applies the lateral force...

...46 A method as in claim 43, farther comprising:
removing the closure device from the **patent** foramen **ovale** through using the
catheter device; and
repositioning the closure device at least partially through the **patent** foramen **ovale** and in contact with tissue adjacent the **patent** foramen **ovale** .

47 A method as in claim 46, wherein removing the closure device comprises:
advancing the **catheter** device over the closure device to straighten the closure
device; and
retracting the **catheter** device to remove the closure device from the **patent** foramen **ovale** .

48 A method as in claim 47, wherein the left atrial portion is straightened before...

...atrial portion is
straightened before the left atrial portion.

50 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
disposing at least a portion of a closure device within the **patent** foramen
ovale ; and

applying lateral, oppositely directed force to tissues at opposite sides of the **patent** foramen **ovale** , using the portion of the closure device disposed in the **patent** foramen **ovale** , so as to bring a septum primum and a septum secundum between the opposite sides...

...maintain the contact between septum primum. and septum secundum.

56 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
advancing a **catheter** device having a proximal end and a distal end through vasculature of a patient to position the distal end adjacent the **patent** foramen **ovale** ; and delivering a self-closing closure device from the **catheter** to contact tissues
adjacent the **patent** foramen **ovale**
wherein the delivered self-closing closure device closes to bring together the tissues the **patent** foramen **ovale** .

57 A method as in claim 56, wherein delivering the self-closing closure device comprises...

...A method as in claim 56, further comprising transmitting energy comprising at least one of **laser** energy, **radio** **frequency** energy, **ultrasound** energy and **microwave** energy from the **catheter** to secure the closure device to the tissues adjacent the patent **foramen** **ovale** .

59 A method as in claim 56, further comprising transmitting **cryogenic** energy or removing energy via cooling from the **catheter** to secure the closure device to the tissues adjacent the **patent** foramen **ovale** .

60 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
34
attaching a closure device to a limbus of...

...of the closure device to hang from the limbus to cover an opening of the **patent** foramen **ovale** .
61 A method as in claim 60 further comprising applying energy to secure the closure...

...of the limbus and other tissues adjacent the patent.

62 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
advancing an elongate **catheter** device through septum primurn tissue near the
patent foram en ovale;
adjusting a retractable delivery arm from the **catheter** device, the delivery arm coupled with a distal end of the **catheter** device via a universal joint; and manipulating the **catheter** device to deploy a spiral needle from the delivery arm into tissues adjacent the **patent** foramen **ovale** to bring the tissues together.

63 A method as in claim 62, wherein the spiral...

...primum and septum secundum tissues.

64 A method as in claim 62, wherein manipulating the **catheter** device comprises turning or twisting the device about its longitudinal axis.
65 Apparatus for treating a **patent** foramen **ovale** , the apparatus comprising:

an elongate **catheter** body having a proximal end and a distal end; and
at least one retractable abrasive needle movable between a retracted position wherein the needle resides wholly within the **catheter** body and a deployed position wherein at least a portion of the needle extends through an opening in the **catheter** body adjacent the distal end.

66 Apparatus as in claim 65, wherein the **catheter** body is passable over a guidewire.

67 Apparatus as in claim 65, wherein the at...

...one retractable abrasive needle comprises at least one serrated edge for abrading tissue adjacent the **patent** foramen **ovale** .
35
. Apparatus as in claim 67, wherein the at least one retractable abrasive needle comprises...

...as in claim 68, wherein each of the multiple needles is individually retractable into the **catheter** body.
70 Apparatus as in claim 65, wherein the at least one retractable abrasive needle is movable relative to the **catheter** body to extend the at least one needle through the **patent** foramen **ovale** and retract the needle back through the **foramen** **ovale** .

71 Apparatus as in claim 65, ffirther comprising at least one visualization device coupled with the **catheter** body near the distal end for visualizing at least one of the **patent** foramen **ovale** and tissue surrounding the **patent** foramen **ovale** .

72 Apparatus for treating a **patent** foramen **ovale** , the apparatus comprising:
an elongate **catheter** body having a proximal end and a distal end; and
at least one energy transmission member coupled with the **catheter** body adjacent the distal end for transmitting energy to contact tissue adjacent the **patent** foramen **ovale** to induce closure of the **patent** foramen **ovale** .

73 Apparatus as in claim 72, wherein the energy transmission member transmits at least one of **laser** energy, **radio** **frequency** energy, **ultrasound** energy and **microwave** energy.
74 Apparatus as in claim 72, wherein the energy transmission member comprises at least one of a **cryogenic** energy transmission member and a cooling member.

75 Apparatus as in claim 72, further comprising at least one retractable needle coupled with the **catheter** body for inserting into the tissue to enhance transmission of energy to the tissue.

76...

...tissue together to enhance transmission of energy to the tissue.

78 Apparatus for treating a **patent** foramen **ovale** , the apparatus comprising:
an elongate **catheter** body having a proximal end and a distal end; and
at least one aperture in the **catheter** body adjacent the distal end for dispensing at least one fluid to contact tissue adjacent the **patent** foramen **ovale** to induce closure of the **patent** foramen **ovale** .

79 Apparatus as in claim 78, wherein the fluid comprises a biocompatible

fluid selected from...
...80 Apparatus as in claim 78, further comprising an expandable balloon coupled with the elongate **catheter** body near the distal. end for inhibiting blood flow through the **patent** foramen **ovale** to enhance contact of the at least one fluid with the tissue.

81 Apparatus for treating a **patent** foramen **ovale** , the apparatus comprising:
an elongate **catheter** body having a proximal end and a distal end; and at least one closure device deployable from the **catheter** body, wherein the closure device attaches to tissue adjacent the **patent** foramen **ovale** and self-closes to bring the tissues together.

82 Apparatus as in claim 8 1...

...8 1, wherein the at least one closure device includes a portion extending within the **patent** foramen **ovale** to apply lateral force to tissue at
37
opposite sides of the **patent** foramen **ovale** , thus bringing together tissue between the opposite sides.

86 Apparatus as in claim 8 1, wherein the **catheter** body is passable over a guidewire.

87 Apparatus as in claim 8 1, ftirther comprising at least one visualization device coupled with the **catheter** body near the distal end for visualizing at least one of the **patent** foramen **ovale** and tissue surrounding the **patent** foramen **ovale** .

88 Apparatus as in claim 8 1, further comprising at least one energy transmission member coupled with the **catheter** body adjacent the distal end for transmitting energy to contact tissue adjacent the **patent** foramen **ovale** .

89 Apparatus as in claim 88, wherein the energy transmission member transmits at least one of **laser** energy, **radio** **frequency** energy, **ultrasound** energy and **microwave** energy.

90 Apparatus as in claim 88, wherein the energy transmission member comprises at least one of a **cryogenic** energy transmission member and a cooling member.

91 Apparatus for treating a **patent** foramen **ovale** comprising a clip expandable from a first dimension to a second larger dimension sized to engage the tissue of the **patent** foramen **ovale** , wherein the clip in the larger dimension applies lateral force to tissue at opposite sides of the **patent** foramen **ovale** to bring tissues between the opposite sides together, and wherein the clip can revert or be made to revert to its first dimension.

92 Apparatus for treating a **patent** foramen **ovale** comprising:
an elongate **catheter** body having a proximal end and a distal end; and at least one force application member coupled with the distal end for applying lateral force to opposite sides of the **patent** foramen **ovale** , thus bringing tissues between the opposite sides into contact.

93 Apparatus as in claim 92...

...member

comprises two opposing arms which deflect laterally to engage the opposite sides of the **patent** foramen **ovale** .
38
. Apparatus as in claim 92 wherein the force application member comprises a detachable closure...

...97 wherein the closure device comprises tissue solder or adhesive.
101. Apparatus for treating a **patent** foramen **ovale** comprising:
an attachnient member for attaching to a limbus of a fossa ovalis of the **patent**
foramen **ovale** ; and
a covering member coupled with the attachment member for extending from the limbus to cover an opening of the **patent** foramen **ovale** .
102. Apparatus as in claim 1 0 1 wherein the covering member comprises:
a support...

...energy delivery means for delivering energy to secure the covering member to tissue adjacent the **patent** foramen **ovale** .
39
. Apparatus as in claim 104 ftirther comprising means for introducing tissue solder or adhesive...

...claim 106 wherein the attachment member comprises
opposable j aws.
108, Apparatus for treating a **patent** foramen **ovale** comprising:
an elongate **catheter** configured to pierce through septum primum tissue adjacent the **patent** foramen **ovale** ;
a retractable delivery arm coupled with a distal end of the elongate **catheter** at
a universal joint; and
a spiral needle coupled with and deployable from the retractable delivery arm, wherein turning the **catheter** deploys the spiral needle into tissue adjacent the **patent** foramen **ovale** . 109. Apparatus as in claim 108, wherein the spiral needle is configured to pierce through...

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01166483 **Image available**
ENERGY BASED DEVICES AND METHODS FOR TREATMENT OF PATENT FORAMEN OVALE
DISPOSITIFS ET PROCEDES FONDES SUR L'APPLICATION D'UNE ENERGIE POUR LE TRAITEMENT DU FORAMEN OVALE PERSISTANT

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RELATED to this application

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Detailed Description
Claims

Detailed Description
... elsewhere within the heart.

[00911 In another embodiment, as shown in Figures 20A-20C, a **catheter** device 180 includes a **catheter** body 182, a left atrial tissue apposition member 184 and a separate right atrialtissueappositionmember186. Fig...

...member 184 from a right atrial view, with left atrial member 184 hooking over the **PFO** into the left atrium. Fig. 20B is a close-up view from the perspective of...

...shows both left atrial member 184 and right atrial member 186 in place for apposing **PFO** tissues. In one embodiment, left atrial member 184 may be rotated (curved arrow) to move the hooked portion along the left atrial surface of the **PFO** to apply energy at multiple locations.

24
[00921 Although the foregoing description is complete and...

Claim
1 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
advancing a **catheter** device to a position in the heart for treating the **patent** foramen **ovale** ;
bringing tissues adjacent the **patent** foramen **ovale** at least partially together using the **catheter** device; and
applying energy to the tissues with the **catheter** device to substantially close the **patent** foramen **ovale** acutely.

2 A method as in claim 1, wherein the tissues are brought together before ...

...5 A method as in claim 4, further comprising:
moving at least part of the **catheter** device to a different position relative to the tissues;
bringing the tissues at least partially...
...comprising repeating the moving, bringing together and applying energy steps at multiple locations along the **patent** foramen **ovale** .

7 A method as in claim 6, wherein the repeated moving, bringing together and applying energy steps are started at a first side of the **patent** foramen **ovale** and continued across the **patent** foramen **ovale** to a second side.
26

8 A method as in claim 7, further comprising biasing at least part of the **catheter** device toward the first side, using a biasing device on the **catheter** , before first bringing the tissues together.

9 A method as in claim 7, wherein moving at least part of the **catheter** body comprises bringing the tissues together between two energy transmission members, wherein the tissues are brought together against a **catheter** body of the **catheter** device, and wherein bringing the tissues together against the **catheter** body pushes the **catheter** body to the different position.

10 A method as in claim 7, wherein moving at least part of the **catheter** device comprises moving at least one energy transmission member to the different position. I 11. A method as in claim IO, wherein moving at least part of the **catheter** device comprises moving two energy transmission members to the different position.

12 A method as in claim 1 1, wherein moving at least part of the **catheter** device further comprises moving a **catheter** body to the different position.

13 A method as in claim 4, further comprising actively...

...the energy has been applied.

14 A method as in claim 1, wherein advancing the **catheter** comprises positioning a first distal portion of the **catheter** in a right atrium of the heart.

15 A method as in claim 14, wherein advancing further comprises advancing a second distal portion of the **catheter** at least partially through the **patent** foramen **ovale** .

16 A method as in claim 15, further comprising advancing the second distal portion through the **patent** foramen **ovale** into the left ventricle.

17 A method as in claim 15, further comprising retracting a **catheter** body or sheath to expose at least the second distal portion.
27

18 A method...

...including moving at least one of the first and second expandable members axially along the **catheter** device toward the other expandable member to bring the tissues together between them.

24 A...

...comprises advancing at least one of the portions into one of the tissues adjacent the **patent** foramen **ovale** .

25 A method as in claim 24, wherein the first distal portion is advanced into...
...first and second distal portions.

28 A method as in claim 1, wherein advancing the **catheter** comprises advancing an expandable distal portion of the **catheter** at least partially through the **patent** foramen **ovale** , the expandable distal portion disposed within a sheath.

29 A method as in claim 28...

...A method as in claim 1, wherein applying energy comprises applying at least one of **radiofrequency** energy, **cryogenic** energy, **resistive heat** energy, **ultrasound** energy, **microwave** energy and **laser** energy.

31 A method as in claim 30, wherein at least one of monopolar **radiofrequency** energy and bipolar **radiofrequency** energy is applied.

32 A method as in claim 30, wherein applying energy comprises energizing a single conductive member of the **catheter** device.

33 A method as in claim 30, wherein applying energy comprises energizing multiple conductive members of the **catheter** device.
34 A method as in claim 30, wherein applying energy comprises: energizing at least one conductive fluid in the **catheter** device; and releasing the conductive fluid from the **catheter** device to contact the tissues.

35 A method as in claim 34, wherein energizing the conductive fluid comprises appl ing **radio** **frequency** energy to the fluid disposed within at least one
yl
expandable member of the **catheter** device.

36 A method as in claim 35, wherein the fluid comprises saline solution.
29...

...a
sufficient amount of energy has been applied to the tissues to substantially close the **patent** foramen **ovale** acutely.

44 A method as in claim 43, further comprising discontinuing the application of energy...

...has been applied.
45 A method as in claim 1, further comprising directly visualizing the **patent** foramen **ovale** and the tissues using at least one visualization device coupled with the **catheter** device.

46 A method of treating a **patent** foramen **ovale** in a heart, the method comprising:
advancing a **catheter** device to a position in the heart for treating the **patent**
foramen **ovale** ;
bringing tissues adjacent the **patent** foramen **ovale** at least partially together
using the **catheter** device;
30
applying energy to the tissues with the **catheter** device while holding the
tissues at least partially together; and
holding the tissues at least partially together for a sufficient time after applying the energy to substantially close the **patent** foramen **ovale** .

47 A **catheter** device for treating a **patent** foramen **ovale** in a heart, the
catheter device comprising:
an elongate **catheter** body having a proximal end and a distal end;
at least one tissue apposition member at or near the **catheter** body distal end for bringing tissues adjacent the **patent** foramen **ovale** at least partially together; and at least one energy transmission member at or near the distal end for applying energy to the tissues to substantially close the **patent** foramen **ovale** acutely.

48 A **catheter** device as in claim 47, wherein the at least one tissue apposition member comprises at least a first tissue apposition member for contacting tissue adjacent the **patent** foramen **ovale** from a right atrium of the heart.

49 A **catheter** device as in claim 48, wherein the at least one tissue apposition member further comprises at least a second tissue apposition member for contacting tissue adjacent the **patent** foramen **ovale** from the right atrium.

50 A **catheter** device as in claim 49, wherein the first and second tissue

apposition members comprise opposable...
...at least one of the first and second members is advancable through tissue adjacent the **patent** foramen **ovale** .

51 A **catheter** device as in claim 50, wherein the first apposition member
advances through septum secundurn tissue and the second apposition member advances through septum primum tissue.

52 A **catheter** device as in claim 48, wherein the at least one tissue apposition member further comprises at least a second tissue apposition member for advancing through the **patent** foramen **ovale** to contact the tissues from a left atrium of the heart.

53 A **catheter** device as in claim 52, wherein at least one of the first and second tissue apposition members comprises an expandable member.
31

54 A **catheter** device as in claim 53, wherein both the first and second tissue apposition members comprise...

...members, and wherein at least one of the expandable members is slidably disposed along the **catheter** body so as to be axially movable toward the other expandable member.

55 A **catheter** device as in claim 53, wherein at least one expandable member includes at least one aperture for releasing conductive fluid to contact the tissues.

56 A **catheter** device as in claim 55, wherein at least one expandable member includes a plurality of small apertures for releasing the conductive fluid.

57 A **catheter** device as in claim 55, wherein one of the first and second
members comprises an...

...member and the shaped portion are brought together to bring the tissues together.

58 A **catheter** device as in claim 57, wherein the deployable shaped portion comprises a shape memory material that changes from an undeployed to a deployed shape when released from the **catheter** body.

59 A **catheter** device as in claim 52, wherein the first and second tissue
apposition members comprise a clamp for clamping the tissues together.

60 A **catheter** device as in claim 52, wherein the first tissue apposition
member has a first deployed...

...when deployed to contact the tissues, caused the tissues to be brought together.

61 A **catheter** device as in claim 60, wherein the first shape comprises approximately a curved hook for curving over an edge of the **patent** foramen **ovale** to apply force to the tissues from the left atrium, and wherein the second shape...

...straight, linear shape for applying pressure to the tissues from the right atrium.

62 A **catheter** device as in claim 52, wherein the first and second tissue
apposition members comprise magnets having opposite polarity.
32
63 A **catheter** device as in claim 52, wherein the first tissue apposition
member comprises a pair of...

...atrium, and the second tissue apposition member comprises a curved member for advancing through the **patent** foramen **ovale** to contact the septum primurn from the left atrium.

64 A **catheter** device as in claim 47, wherein the at least one tissue apposition member comprises:
at...

...one biasing member for biasing the tissue apposition members toward a first side of the **patent** foramen **ovale** .

65 A **catheter** device as in claim 64, wherein the tissue apposition members are movable along the **patent** foramen **ovale** from the first side to a second opposite side of the **patent** foramen **ovale** .

66 A **catheter** device as in claim 65, wherein the **catheter** body has a crosssectional shape such that when the tissues are brought together between the two tissue apposition members, the tissues urge the **catheter** body to a different position relative to the **patent** foramen **ovale** .

67 A **catheter** device as in claim 66, wherein the shape is selected from the group consisting of triangular, oval, elliptical and diamond shaped.

68 A **catheter** device as in claim 66, wherein the two tissue apposition members comprise:
one shape-memory tissue apposition member; and
one jaw member.

69 A **catheter** device as in claim 66, further comprising at least one aperture on the **catheter** body for releasing one or more fluids to enhance the application of energy to the tissues to close the **patent** foramen **ovale** .
33

70 A **catheter** device as in claim 66, further comprising a coating over the **catheter** body, the coating enhancing application of energy to the tissues when the tissues contact the **catheter** body.

71 A **catheter** device as in claim 47, wherein the at least one tissue apposition member comprises an expandable member releasably disposed within the **catheter** body, wherein advancing the expandable member out the distal end of the **catheter** body or retracting the **catheter** body relative to the expandable member allows the expandable member to expand within the **patent** foramen **ovale** .

72 A **catheter** device as in claim 71, wherein the expandable member comprises two prongs that expand apart to provide lateral force to the tissues adjacent the **patent** foramen **ovale** .

73 A **catheter** device as in claim 72, wherein the prongs do not extend into the left atrium of the heart.

74 A **catheter** device as in claim 72, wherein the prongs are spring loaded.

75 A **catheter** device as in claim 72, wherein the prongs comprise a shape memory material.

76 A **catheter** device as in claim 72, wherein the prongs include at least one vacuum aperture for applying vacuum force to further bring the tissues together.

77 A **catheter** device as in claim 47, further comprising a guide member for advancing through the **patent** foramen **ovale** , wherein the **catheter** device is slidably disposed over the guide member.

78 A **catheter** device as in claim 77, wherein the guide member comprises a guidewire divided along a portion of its length, the divided portion comprising expandable shape memory material.

79 A **catheter** device as in claim 77, wherein the guide member comprises at least one tip for contacting a left atrial surface of the tissues adjacent the **patent** foramen **ovale** .

80 A **catheter** device as in claim 79, wherein the at least one tip is conformable to the left atrial surface.

81 A **catheter** device as in claim 79, wherein the guide member is retractable to engage the at least one tip with the left atrial surface.

82 A **catheter** device as in claim 77, wherein the guide member comprises at least one of the energy transmission member(s).

83 A **catheter** device as in claim 82, wherein the guide member comprises an expandable member for expanding within the patent **foramen** **ovale** , and wherein the expandable member comprises at least one **radiofrequency** energy transmission member.

84 A **catheter** device as in claim 47, wherein the at least one energy transmission member transmits at least one of **radiofrequency** energy, **cryogenic** energy, **resistive** **heat** energy, **ultrasound** energy, **microwave** energy and **laser** energy.

85 A **catheter** device as in claim 84, wherein the at least one energy transmission member is movable relative to the at least one tissue apposition member.

86 A **catheter** device as in claim 84, wherein the at least one energy transmission member is coupled with the at least one tissue apposition member.

87 A **catheter** device as in claim 84, wherein the at least one energy transmission member comprises the at least one tissue apposition member.

88 A **catheter** device as in claim 84, wherein the at least one energy transmission member comprises at least one monopolar **radiofrequency** transmission member.

89 A **catheter** device as in claim 84, wherein the at least one energy transmission member comprises at least two bipolar **radiofrequency** transmission members.

90 A **catheter** device as in claim 84, wherein the at least one energy transmission member comprises:
at least one **radiofrequency** transmission member disposed within an expandable member, the expandable member including at least one aperture ...

...35
at least one conductive fluid disposed within the expandable member and exposed to the **radiofrequency** transmission member.

91 A **catheter** device as in claim 84, wherein the at least one energy transmission member comprises at least one curved **radiofrequency** transmission member.
92 A **catheter** device as in claim 84, wherein the at least one energy transmission member comprises at least one of a mesh material and a braid material.

93 A **catheter** device as in claim 47, wherein the at least one energy transmission member comprises a guide member for advancing through the **patent** foramen **ovale** .

94 A **catheter** device as in claim 93, wherein the guide member includes at least one expandable portion for expanding within the **patent** foramen **ovale** to at least partially bring together the tissues adjacent the **patent** foramen **ovale** .

95 A **catheter** device as in claim 47, further comprising at least one sensor coupled with the **catheter** device for sensing an amount of energy delivered to the tissues by the at least one energy transmission member.

96 A **catheter** device as in claim 95, wherein the at least one sensor is selected from the group consisting of an infrared sensing device, thermistors and thermocouples.

97 A **catheter** device as in claim 95, further comprising a microprocessor coupled with the at least one...

...when the amount of delivered energy has reached a desired amount of energy.

98 A **catheter** device as in claim 47, further comprising a microprocessor coupled with the **catheter** device for sensing and controlling energy transmission by the energy transmission member.

99 A system for treating a **patent** foramen **ovale** in a heart, the system comprising:
a **catheter** device comprising:
an elongate **catheter** body having a proximal end and a distal end;
36
at least one tissue apposition member at or near the **catheter** body distal end for bringing tissues adjacent the **patent** foramen **ovale** at least partially together; and

at least one energy transmission member at or near the distal end for applying energy to the tissues to substantially close the **patent** foramen **ovale** ; and at least one guide member for guiding the **catheter** device to a position for treating the **patent** foramen **ovale** . I 1 100. A system as in claim 99, wherein the at least one tissue apposition member comprises at least a first tissue apposition member for contacting tissue adjacent the **patent** foramen **ovale** from a right atrium of the heart. 101. A system as in claim 100, wherein...

...member further comprises at least a second tissue apposition member for contacting tissue adjacent the **patent** foramen **ovale** from the right atrium.
102. A system as in claim IO 1, wherein the first...

...at least one of the first and second members is advancable through tissue adjacent the **patent** foramen **ovale** .
103. A system as in claim 102, wherein the first apposition member advances through septum...

...member further comprises at least a second tissue apposition member for contacting tissue adjacent the **patent** foramen **ovale** from a left atrium of the heart.
105. A system as in claim 104, wherein the second tissue apposition member is advancable through the **patent** foramen **ovale** into the left atrium to contact the tissue. 106. A system as in claim 105...

...and wherein at least one of the
37
expandable members is slidably disposed along the **catheter** body so as to be axially movable toward the other expandable member.
108. A system...

...memory material that changes from an undeployed to a deployed shape when released from the **catheter** body.
112. A system as in claim 104, wherein the first and second tissue apposition...

...one biasing member for biasing the tissue apposition members toward a first side of the **patent** foramen **ovale** . 114. A system as in claim II 3, wherein the tissue apposition members are movable along the **patent** foramen **ovale** from the first side to an opposite side of the **patent** foramen **ovale** .
115. A system as in claim 99, wherein the at least one tissue apposition member comprises an expandable member releasably disposed within the **catheter** body, wherein advancing the expandable member out the distal end of the **catheter** body allows the expandable member to expand within the **patent** foramen **ovale** .
38
116. A system as in claim 115, wherein the expandable member comprises at least two members that expand apart to provide lateral force to the tissues adjacent the **patent** foramen **ovale** .
117. A system as in claim 116, wherein the exposed expanding member provides the lateral...

...120. A system as in claim 99, wherein the guide member is advancable through the **patent** foramen **ovale** , wherein the **catheter** device is slidably disposed over the guide member.
121. A system as in claim 120...

...at

least one tip for contacting a left atrial surface of the tissues adjacent the **patent** foramen **ovale** . 123. A system as in claim 122, wherein the at least one tip is conformable...

...claim 99, wherein the at least one energy transmission member transmits at least one of **radiofrequency** energy, **cryogenic** energy, **resistive heat** energy, **ultrasound** energy, **microwave** energy and **laser** energy. 126. A system as in claim 125, wherein the at least one energy transmission...

...claim 127, wherein the at least one energy transmission member comprises at least one monopolar **radiofrequency** transmission member. 129. A system as in claim 127, wherein the at least one energy transmission member comprises at least two bipolar **radiofrequency** transmission members. 130. A system as in claim 127, wherein the at least one energy transmission
member comprises:
at least one **radiofrequency** transmission member disposed within an expandable member, the expandable member including at least one aperture ...

...and
at least one conductive fluid disposed within the expandable member and exposed to the **radiofrequency** transmission member. 131. A system as in claim 127, wherein the at least one energy transmission member comprises at least one curved **radiofrequency** transmission member. 132. A system as in claim 127, wherein the at least one energy...

...A system as in claim 99, further comprising at least one sensor coupled with the **catheter** device for sensing an amount of energy delivered to the tissues by the at least...

...40
136. A system as in claim 99, further comprising a microprocessor coupled with the **catheter** device for sensing and controlling energy transmission by the energy transmission member.
41

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00913895 **Image available**
MICROELECTRODE CATHETER **FOR MAPPING AND ABLATION**
CATHETER **A MICROELECTRODES POUR CARTOGRAPHIE OU ABLATION**
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MICROELECTRODE CATHETER **FOR MAPPING AND ABLATION**
CATHETER **A MICROELECTRODES POUR CARTOGRAPHIE OU ABLATION**
Main International Patent Class: **A61B-018/14**
Fulltext Availability:
Detailed Description
Claims

English Abstract
Catheter for mapping and/or ablation, and methods of using the same. According to one embodiment, **catheter** includes a metallic cap having a plurality of apertures and at least one **electrode** disposed in each aperture of the plurality of apertures. According to another embodiment, the **catheter** includes a non-conductive cap having a plurality of apertures and at least one **electrode** disposed in each aperture of the plurality of apertures. **Electrodes** may be paired, arranged along the length of the cap, or circumferentially arranged on the...

...a further embodiment, a method for treating a condition of a heart includes placing a **catheter** inside the heart, mapping a region of the heart using mapping **electrodes** on the **catheter** , and ablating using an ablation **electrode** disposed about the mapping **electrodes** of the **catheter** .

French Abstract

L'invention concerne un **catheter** pour cartographie et/ou ablation, et des procedes mettant en oeuvre ce **catheter** . Selon un mode de realisation, le **catheter** comprend une capsule metallique presentant plusieurs orifices et au moins une **electrode** disposee dans chaque orifice. Selon un autre mode de realisation, le **catheter** comprend une capsule non conductrice presentant plusieurs orifices et au moins une **electrode** disposee dans chaque orifice. Les **electrodes** peuvent etre organisees par paires et disposees sur la longueur de la capsule, ou sur ...

...l'invention concerne un procede de traitement d'une cardiopathie, qui consiste a placer un **catheter** a l'interieur du coeur; a cartographier une zone du coeur au moyen d' **electrodes** de cartographie disposees sur le **catheter** ; et a pratiquer une ablation au moyen d'une **electrode** d'ablation disposee autour des **electrodes** de cartographie du **catheter** .

Detailed Description

MICROELECTRODE **CATHETER** FOR MAPPING AND ABLATION

Cross Reference To Related Applications

This application claims the benefit of U.S. provisional application serial no.

5 60/254@630 entitled "Microelectrode **Catheter** for Mapping, Ablation, and Localization," filed December 1 1, 2000, which is hereby incorporated herein...

...invention relates to methods and apparatus for performing mapping and ablation procedures using a single **catheter** .

2. Discussion of the Related Art

The human heart is a very complex organ, which...

...first deten-nined by endocardial map iing techniques. Mapping typically involves

p

percutaneously introducing a **catheter** having one or more **electrodes** into the patient, passing the **catheter** through a blood vessel (e.g. the femoral vein or artery) and into an endocardial...

...that cardiac arrhythmias emanating from that region can be blocked by ablating tissue.

An ablation **catheter** with one or more **electrodes** can then transmit electrical energy to the tissue adjacent the **electrode** to create a lesion in the tissue. One or more suitably positioned lesions will typically...

...impulse caused by the arrytbromogenic focus. Ablation is carried out by applying energy to the **catheter** **electrodes** . The ablation energy can be, for

example, **RF** , DC, **ultrasound** , **microwave** , or **laser** radiation.,

Summary Of The Invention

The present invention encompasses apparatus and methods for mapping electrical...

...errant electrical impulses caused by an arrhythmia.

In one embodiment, the present invention includes a **catheter** comprising a metallic cap including a plurality of apertures and at least one

electrode disposed in each aperture of the plurality of apertures.

According to another embodiment of the invention, the **electrodes** are insulated from the cap.

According to another embodiment of the invention, the **electrodes** extend beyond a surface of the cap.

@ According to another embodiment of the invention, the **electrodes** are mushroomshaped.

According to another embodiment of the invention, the **electrodes** are domeshaped.
According to another embodiment of the invention, the cap is gold.

According to...

...of the invention, the cap is platinum.

According to another embodiment of the invention, the **catheter** farther comprises means for steering a distal end of the **catheter** .

According to another embodiment of the invention, the means for steering includes means for steering a distal end of the **catheter** in at least one plane.

According to another embodiment of the invention, the metallic cap may be used to perform ablation and the at least one **electrode** disposed in each aperture may be used to perform mapping.

According to another embodiment of...

...metallic cap is
constracted and arranged to optimize ablation procedures and wherein a configuration of **electrodes** is selected to optimize mapping procedures.
According to another embodiment of the invention, a surface...

...of the metallic cap is larger than a surface area of the at least one **electrode** .

According to another embodiment of the invention, the **catheter** further comprises a localization sensor for identifying a location of the **catheter** .

According to another embodiment of the invention, the **catheter** farther comprises a temperature sensor for sensing temperature in a vicinity of the **catheter** .

According to another embodiment of the invention, the **catheter** farther comprises
a temperature sensor for sensing temperature in a vicinity of the cap. '
According to another embodiment of the invention, the **catheter** comprises means for irrigating in a vicinity of the **catheter** .

According to another embodiment of the invention, the **catheter** comprises means for irrigating in a vicinity of the cap.
In another embodiment, the invention includes a **catheter** farther comprising a substantially cylindrical cap portion; a substantially dome-shaped cap portion disposed distal to the substantially cylindrical cap portion and first and second **electrodes** mounted to the

substantially dome-shaped cap portion, but not to the substantially cylindrical cap portion.

According to another embodiment of the invention, the **catheter** further comprises a reference **electrode** mounted to the cylindrical cap portion.

According to another embodiment of the invention, the **catheter** has an axis that extends longitudinally along a length of the **catheter** and further includes at least one group of **electrodes** mounted to the cylindrical cap ...plane normal to the axis.

According to another embodiment of the invention, a plurality of **electrodes** mounted along a line that is parallel to the axis.

In another embodiment, the invention includes a method for treating a condition of a heart, comprising acts of placing a **catheter** inside the heart, mapping a region of the heart, using mapping **electrodes** on the **catheter** , and ablating, using an ablation **electrode** disposed about the mapping **electrodes** of the **catheter** .

In another embodiment, the invention includes a method of creating a lesion in heart tissue and determining a continuity of the lesion, comprising acts of providing a **catheter** having at least one ablation **electrode** and a plurality of mapping **electrodes** , placing the plurality of **electrodes** in contact with the heart tissue at the location of the lesion, creating a lesion in the heart tissue using the at least one ablation **electrode** , detecting a signal from each of the plurality of **electrodes** , determining, based on the signal from each of the plurality of **electrodes** , whether a signal exists between any adjacent **electrodes** , and assessing the continuity of the lesion.

In another embodiment, the invention includes a method of determining a location for a septal wall puncture, comprising acts of providing a **catheter** with first and second **electrodes** on a distal tip of the **catheter** , detecting a signal from each of the first and second **electrodes** , and determining, based on the signal from each of the first and second **electrodes** , an area of lowest conductivity on the septal wall.

Brief Description Of The Drawings
In...

...been given like reference characters,
Figure I illustrates an overview of a mapping and ablation **catheter** system in
accordance with the present invention;
Figure 2 illustrates a side view of the distal cap portion of the **catheter** of Figure 1
in accordance with one embodiment of the present invention;
Figure 3 illustrates an end view of the distal cap portion of the **catheter** of Figure
2;
Figure 4 illustrates a cross-sectional side view of the of the distal cap portion of
the **catheter** of Figure 2;
Figure 5 illustrates a cross-sectional end view of the distal cap portion of the
catheter of Figure 2;
Figure 6 illustrates a partial cross-sectional side view of the distal cap portion of a

catheter in accordance with another embodiment of the present invention;
Figure 7 illustrates a partial cross-sectional side view of the distal. cap portion of a **catheter** in accordance with a another embodiment of the present invention; Figure 8 illustrates a partial cross-sectional side view of the distal. cap portion of a
catheter in accordance with another embodiment of the present invention;
Figure 9 illustrates a perspective view of the distal cap portion of a **catheter** in
accordance with another embodiment of the present invention;
Figure 10 illustrates a perspective view of the distal cap portion of a **catheter** in
accordance with another embodiment of the present invention;
Figure I 1 illustrates a perspective view of the distal. cap portion of a **catheter** in
accordance with another embodiment of the present invention;
Figure 12 illustrates a side cross-sectional view of the distal cap portion of a
catheter in accordance with another embodiment of the present invention;
Figure 13 illustrates'insertion of the **catheter** of the present invention into a body;
and
Figure 14 illustrates the insertion of the **catheter** of the present invention into the heart.

Detailed Description
In this description, various aspects and...

...on the particular application. Furthermore, any of the various features may be incorporated in a **catheter** and associated method of use for mapping and/or ablation procedures.

Catheter Overview
Reference is now made to Figure 1, which illustrates an overview of a mapping and ablation **catheter** system for use in electrophysiology procedures, in accordance with the present invention. The system includes a **catheter** 1 having a shaft portion 3, a control handle 5, and a connector portion 7...

...in mapping applications, connector portion 7 is used to allow signal wires running from mapping **electrodes** at the distal end 6 of the **catheter** to be connected to a device for recording signals, such as a recording device 17...
...in ablation applications, connector portion 7 is used to allow signal wires running from ablation **electrodes** at the distal end 6 of the **catheter** to be connected to a device for generating ablation energy, such as ablation energy generator...

...portion 7 via cable 1 1. In one embodiment, controller 9 may be a QUADRAPULSE **RF** CONTROLLERTIII device available from C.R. Bard, Inc., Murray Hill, New Jersey. Ablation energy generator...

...controller 9 is used to control ablation energy, provided by ablation energy generator 13, to **catheter** 1. When used in a mapping application, controller 9 is used to process signals from **catheter** 1 and provide these signals to recording device 17. Although illustrated as separate devices, recording...

...illustrated in Figure 1, either or both of these devices may be incorporated in the **catheter** system in accordance with the present invention.

The shaft portion 3 of the **catheter** 1 is, in one embodiment, approximately seven French in diameter, although it should be appreciated incorporated into the **catheter** . Shaft portion 3 includes a distal cap portion 21 having a plurality of, for example, two or more **electrodes** . As will be subsequently described, the **electrodes** may be arranged in a number of different configurations and may include mapping and/or ablation **electrodes** .

According to one embodiment of the invention, distal cap portion 21 is approximately eight mm...

...3, which respectively illustrate a side elevation view of the distal cap portion 21 of **catheter** I along line B-B of Figure 1, and an end elevation view of the distal cap portion 21 of **catheter** I along line D-D of Figure 2. Distal cap portion 21 is provided, in the illustrated embodiment, with a first set of mapping **electrodes** 47, a second set of mapping **electrodes** 49, and a band **electrode** 5 1.

The **electrodes** may be formed of any suitable bio-compatible, electrically conductive material (e.g., platinum, gold, titanium, iridium, stainless steel). The mapping **electrodes** 47, 49 are approximately 0 1.5 mm in diameter, though they may be either larger or smaller according to the invention. The size of mapping **electrodes** 47, 49 is in part determined based on considerations of signal quality, which improves as **electrode** size increases and as **electrode** isolation (i.e., distance between **electrodes**) increases.

The **electrodes** may have any of numerous shapes. hi Figure 2, mapping **electrodes** 47, 49 are shown having a circular shape. However, mapping **electrodes** 47, 49 may alternatively be square, oval, hexagonal, octagonal, or any other shape that may be readily imagined by one skilled in the art. Further, though mapping **electrodes** 47, 49 -are- also shown in Figure 2, as well as Figures 3-5 and 7-12, as dome-shaped, the mapping **electrodes** of any of the illustrated embodiments may alternatively be flat so that they are more...

...with the surface of the distal cap portion 21, as shown, for example, by mapping **electrodes** 48, 50 in Figure 6. Band **electrode** 51 is shown in Figure 2 as flat, but may alternatively have a curved surface...

...5, which respectively illustrate a crosssectional side view of the distal cap portion 21 of **catheter** 1 along line E-E of Figure 3, and a cross-sectional axial view of the distal cap portion 21 of **catheter** I along line F-F of Figure 4. As shown, wires 52, 53, 54 respectively connect to each of the **electrodes** 47, 49, 51 of the **catheter** 1. These wires 52, 53, 54, which may be between 3/1000 min and 20/1000 mm, allow electrical signal information to be transmitted from mapping **electrodes** 47, 49 and band **electrode** 5 1, when used in a mapping application, to connector portion 7, which in turn connects to controller 9 (Figure 1). When **electrode** 51 is used in an ablation application, the wire 54 connected thereto may be used to transmit ablation energy from ablation energy generator 13 to the **electrode** via connector portion 7. The wires 52, 53, 54 are connected to the **electrodes** by soldering, welding, or any other suitable mechanism for connecting the wires to the **electrodes** to form an electrical connection. Mapping **electrodes** 47, 49 may be substantially mushroornshaped, and may have a substantially cylindrical "stem" portion 48. As shown in Figures 4 and 5, the cylindrical stem 48 of each **electrode** 47, 49 may have a larger diameter at the base 46 of the stem, so that the **electrode** is prevented from dislodging from the distal cap portion 21. Distal cap portion 21 may also be countersunk at the location of each **electrode** , so that the **electrodes** are disposed within a recessed portion of the distal cap portion 2 1.

Mapping **electrodes** 47, 49 and band **electrode** 51 are disposed in apertures within a distal cap 57, which covers the distal cap portion 21 of the **catheter** 1. The distal cap 57 may be, in one embodiment, formed of any non-electrically...

...material. In addition to providing a durable surface, distal cap 57 isolates each of the **electrodes** on distal cap portion 21 from each other.

According to one aspect of the invention, the distal cap portion 21 is provided with a pair of mapping **electrodes** 47 at the distal end of **catheter** 1. The pair of mapping **electrodes** 47, in accordance with one embodiment of the invention, are disposed on the dome-shaped...

...not on the cylindrically-shaped portion 22 of the distal cap 57. Further, the mapping **electrodes** 47 may be positioned, in one embodiment, at a 45' angle with respect to an axis C-C that extends longitudinally along the length of **catheter** 1, through its center. The mapping **electrodes** 47 may be separated by a distance of approximately 1 mm. One skilled in the art will appreciate that other angles and separation distances for mapping **electrodes** 47 may be provided.

The pair of mapping **electrodes** 47 may be used to determine, for example, a location of lowest conductivity on the...

...preferred location to puncture the septal wall during a transeptal procedure. Each of the mapping **electrodes** 47 may detect a voltage signal, which is transmitted to controller 9 via wires 53. Voltage may be measured instantaneously or continuously by each of the **electrodes** 47. Continuous voltage measurements generate an electrograirn (a voltage signal that changes with time) for each **electrode** 47. The voltage detected by each **electrode** 47 may be determined with respect to a reference **electrode** , termed a unipolar voltage measurement, or may be determined with respect to the other **electrode** 47 of the pair, termed a bipolar voltage measurement. Thus, the pair of mapping **electrodes** 47 may generate two unipolar electrograms, each with respect to a reference **electrode** located elsewhere on the **catheter** 1, or a single bipolar electrogram representing the voltage between each of the **electrodes** 47 of the pair.

In the bipolar mode, the use of two **electrodes** 47 enables the voltage between the **electrodes** to be determined. hi the unipolar arrangement, the use of two **electrodes** enables an additional data point for locating the preferred site of puncture. For example, if a first **electrode** of the pair detects a lower amplitude signal than the second **electrode** of the pair, this information can be used to indicate that the distal cap portion 21 of **catheter** 1 should be moved in the direction of the first **electrode** , towards the lower amplitude signal. It should be appreciated that while the **electrodes** 47 are described as a pair of **electrodes** , a single **electrode** or more than two **electrodes** may alternately be used on the distal cap portion 21 in accordance with the invention...

...is represented by a reduced or minimized voltage signal from one or more of the **electrodes** 47. This point may be detected by a computer algorithm and/or a human operator...

...a point of lowest conductivity or a preferred site of puncture.

We have found that **electrodes** approximately one mm in size, spaced approximately one mm apart and set at approximately 45' with respect to axis c-c advantageously allows for accurate determination of the **foramen ovale** during transeptal procedures.

According to another aspect of the invention, the distal. cap portion 21 is provided with a group of mapping **electrodes** 49 circumferentially disposed about the distal cap portion 21 of **catheter** 1. Reference is now made to Figures 2 through 12, which respectively illustrate side and ...

...distal. cap portion 21 according to this aspect of the invention. The group of mapping **electrodes** 49 are disposed on the cylindrically-shaped portion 22 of the distal. cap portion 21...
...plane (e.g. F-F) normal to the axis C-C (Figure 4). The mapping **electrodes** 49 may be equidistant from each - 10 other and may be separated by a distance of at least half of the diameter of each **electrode** . In one embodiment, the group of mapping **electrodes** 49 includes four **electrodes** , though other numbers of **electrodes** (e.g., two, three, five, six) are also possible according to the invention.

According to...

...invention, the distal cap portion 21 is provided with a plurality of groups of mapping **electrodes** 49 circumferentially disposed about the distal cap portion 21 of **catheter** 1. As illustrated in Figure 1 0, **catheter** I may be provided with four groups of mapping **electrodes** 49, which may, for example, comprise four **electrodes** each. The spacing of groups of **electrodes** 49 is, in one embodiment, approximately two millimeters.

One or more groups of mapping **electrodes** 49 may be used to determine the
intensity, direction, and velocity of electrical signals of the heart. The group configuration of mapping **electrodes** 49 provides advantages over certain **electrodes** , e.g., band **electrodes** , which do not allow the same degree of differentiation between signals.

For example, a band **electrode** cannot differentiate signals received from a various regions of the circumference of the **catheter** . In contrast, a group of four **electrodes** allows differentiation between signals from each quadrant of the circumference of the **catheter** , and therefore provides more directional inforination than a band **electrode** .

Multiple groups of mapping **electrodes** 49 allows a greater degree of differentiation between signals received at various points along the length of a **catheter** . Further, because the signals received by different **electrodes** may be compared, the propagation of a signal along the length of the **catheter** may be tracked, and intensity, direction, and velocity of the propagating electrical signals may be calculated. Groups of mapping **electrodes** also allows for differentiation between signals of local and remote origin, based on a comparison of signals received by adjacent **electrodes** . For example, if a signal is measured more weakly by each successive adjacent **electrode** , and received after a constant time lapse by each successive **electrode** , one may detennine that the signal is of remote origin (i.e., a "far-field" signal). In contrast, if a signal is received more strongly by a particular **electrode** than adjacent **electrodes** , and is not received earlier by an adjacent **electrode** , one may determine that the signal is of local origin (i.e., a "nearfield" signal). Thus the configuration of mapping **electrode** 49 can provide a high resolution mapping **catheter** .

According to another aspect of the invention, the distal cap portion 21 is provided with a row of mapping **electrodes** 61 disposed along the length of distal cap portion 21.

As illustrated in Figure 1 1, each **electrode** 61 may be equidistant from each adjacent **electrode** disposed along the length of the **catheter** 1. The **electrodes** 61 may be similar to the **electrodes** of other embodiments, and may be approximately between 0. 5 and 1. 5 mm in diameter. In one embodiment, the **catheter** is provided with four mapping **electrodes** 61 disposed on the circumference of distal cap portion 21, although more or fewer mapping **electrodes** 61 may be used. The spacing of the **electrodes** 61 is, in one embodiment, approximately one mm.

The rows of mapping **electrodes** 61 that extend along the length of distal cap portion 21 may be used to...

...burn" ablation technique. A voltage signal may be measured between each of the adjacent mapping **electrodes** 61 in a row of **electrodes** . The controller 9 may process each voltage signal and, for example, determine whether the voltage...indicating that a gap in the lesions may exist.

More generally, the row of mapping **electrodes** 61 may be used to determine the conductivity of the heart tissue in contact with the **electrodes** for any portion of heart tissue between any adjacent or non-adjacent pair of **electrodes** 61.

According to another aspect of the invention, the distal cap portion 21 is provided with a band-shaped **electrode** disposed on the distal cap 57 of **catheter** 1. As illustrated in Figures 2 through 12, the band-shaped **electrode** 51 may serve as a reference **electrode** for other **electrodes** on the **catheter** 1, whereby other voltages of other **electrodes** are determined relative to band-shaped **electrode** 5 1. In another embodiment of the invention, the band-shaped **electrode** serves as an ablation **electrode** and is provided with ablation energy to perform ablation. Reference is now made to Figure 6, which illustrates a band-shaped ablation **electrode** 63. The band-shaped ablation **electrode** 63 may be provided with **RF** energy for ablation, and may be at least 4 mm in length to facilitate ablation. In a ffirther embodiment of the invention, a band-shaped ablation **electrode** and a band-shaped temperature sensor are provided. Reference is now made to Figure 7, which illustrates a band-shaped ablation **electrode** 65 and a band-shaped temperature sensor 67. Temperature sensor 67 may be a thermocouple...

...sensor 67 detects the heat of - 12 the tissue during ablation by band-shaped ablation **electrode** 65. Temperature sensing is important during ablation because overheated tissue may explode or char, releasing debris into the bloodstream. Band-shaped ablation **electrode** 65 is connected to connector portion 7 via wire 66, which in turn connects to ...

...portion 7 via wire 68, which in turn connects to ablation controller 9. Band-shaped **electrode** 51 can serve as both a reference **electrode** and an ablation **electrode** , and may be switched between applications by the controller 9 or by a human operator...

...electrically conductive material.

As illustrated in Figure 12, distal cap 57 is disposed about mapping **electrodes** 47, 49 and band-shaped **electrode** 5 1. Distal cap 57 is connected via wire 75 to connector portion 7, which...

...compatible, electrically conductive material (e.g., platinum, gold, titanium, iridium, stainless steel). To insulate mapping **electrodes** 47, 49 and band-shaped **electrode** 51 from conductive distal cap 57, insulating sleeves 77 and insulating sleeves 79 are respectively provided. Insulating sleeves 77 and insulating sleeves 79 may extend beyond mapping **electrodes** 47, 49 and band-shaped **electrode** 51 over the surface of distal cap 57 in a gasket-like formation. When **RF** ablation energy is delivered to conductive distal cap 57, as will be described below, **RF** energy may concentrate at the edges of the apertures distal cap 57. Insulation of the...

...ablation energy to a desired area of tissue. The ablation energy can be, for example, **RF** , DC, **ultrasound** , **microwave** , or **laser** radiation. Ablation may be performed in a blood vessel, e.g., the pulmonary vein, or ...

...tissue that is in contact with the distal cap portion 21, For example, if an **electrode** on distal cap portion 21 detects an arrhythinia focus site in the vicinity of the **electrode** , the region of the distal cap 57 that is closest to the **electrode** may be used to ablate the tissue. Advantageously, repositioning of the **catheter** I is not necessary - 13 between detection of an arrhythmia focus site via a mapping **electrode** and ablation of the arrhythinia focus site via conductive distal cap 57. Further, because ablation...

...in less extensive tissue scarring.

The embodiment illustrated in Figure 12 has several advantages. The **catheter** is able to provide two functions, mapping and ablation, in a single **catheter** wherein the **catheter** is constructed and arranged to provide each of these functions individually and independently. The design of the **catheter** for high resolution mapping functions does not adversely impact the design for ablation functions. The **catheter** can be constructed so as to optimize each function. For example, the small size and location of each mapping **electrode** 49 on the distal cap portion 21 may be chosen to provide the ability to...

...high resolution and an appropriate level of tissue contact, but without interference from either adjacent **electrodes** or other tissue not of interest.

For ablation procedures, it is desirable to have a...

...meet these requirements since its surface area and mass are significantly larger than the mapping **electrodes** 49. Incorporating the small mapping **electrodes** 49 into apertures in the larger conductive distal cap 57 allows mapping and ablation procedures to be performed with a single **catheter** . hi addition, since the mapping **electrodes** and the conductive distal cap can be operated independently, mapping and ablation procedures can be after each other.

Steerinor
Catheter I may be a steerable device. Reference is again made to Figure 1, for description of one possible implementation for a steering mechanism for **catheter** 1.

Catheter 1 is connected to **catheter** handle 5, which enables steering control of the distal end of **catheter** 1. In one embodiment of the invention, a control switch 23 is mechanically coupled to...

...25, which is in turn mechanically coupled to the distal cap portion 21 of the **catheter** 1. As shown in Figure 6, an anchor 59 may be provided in the distal cap portion 21 to fix the steering wire 25 to the inside of the - 14 **catheter** 1. The tension on the steering wire 25 may be adjusted by the control switch 23 to adjust a flexible portion of the distal end of the **catheter** 1. In particular, the control switch 23 may be maneuvered laterally along the control handle 5 to control the curvature of the distal end of the **catheter** 1. For example, the control switch 23 may be slid towards the proximal end of **catheter** 1 to move the distal. end of the **catheter** 1 to position 27, and towards the distal end of control handle 5 to move the distal end of the **catheter** 1 to position 29. The control switch 23 may be slid to a position midway between the forward and backwards positions to orient the distal end of the **catheter** I in an uncurved position.

I 0 It should be appreciated that, although steering in a single plane is illustrated in Figure 1, the **catheter** may be steered in any number of directions, in one or more planes.

Further, although...

...may be implemented on the control handle 5, or via a device external to the **catheter** assembly. U.S. Patent Numbers 5,383,852, 5,462,527, and 5,611,777...

...various additional embodiments and features of control handle 5 that may be used for steering **catheter** 1.

Localization
Localization refers to a number of techniques whereby the location of **catheter** 1 in a patient can be determined. Apparatus and methods for localization can be incorporated into **catheter** 1.

Reference is now made to Figure 8, which illustrates a cross-sectional view of the distal cap portion 21 of **catheter** 1 including an electromagnetic sensor 69 that may be used for localization. Electromagnetic sensor 69, may be fixed within the shaft of the **catheter** 1 using any suitable mechanism, such as glue or solder. The electromagnetic sensor 69 generates...

...the controller 9 for processing.

In addition to the electromagnetic sensor 69 fixed to the **catheter** , a second electromagnetic sensor (not shown) is provided that is fixed relative to the patient...

...field.

Signals generated by the reference electromagnetic sensor and electromagnetic sensor 69 fixed to the **catheter** are analyzed by the controller 9 to ascertain a precise location of electromagnetic sensor 69 fixed to the **catheter** 1.

Further, the signals can be used to generate a contour map of the heart. The map may be generated by contacting the **catheter** 1 with the heart tissue at a number of locations along the heart wall. At...

...the controller 9, or to another processor, to determine and record a location of the **catheter** 1. The contour map is generated by compiling the location information for each point of contact. This map may be correlated with heart signal data, measured by one or more **electrodes** on the **catheter** , for each location to generate a map of both the shape and electrical activity of...

...generated by the electromagnetic sensors may also be analyzed to determine a displacement of the **catheter** 1 caused by heartbeat.

As an alternative to the use of electromagnetic sensors other conventional techniques, such as **ultrasound** or magnetic resonance imaging (NM) can also be used for localization of **catheter** 1.

In addition, an impedance-based sensor can also be incorporated into **catheter** 1.
In an impedance-based system, several, such as three, high frequency signals are generated along different axes. The **catheter** **electrodes** may be used to sense these frequencies, and with appropriate filtering, the strength of the signal and thus the position of the **catheter** can be determined.

One skilled in the art will appreciate that the construction of **catheter** 1 may be optimized to make use of the various localization techniques.

Irrigatio
Irrigation refers...

...the vicinity surrounding distal cap 21. Apparatus and methods for irrigation can be incorporated into **catheter** 1. The fluid may be a contrast fluid, a cooling fluid (particularly during ablation procedures ...

...inside shaft portion 3 that transports the irrigation fluid fi-om the proximal end of **catheter** I to distal cap 21.

The irrigation fluid may be dispersed into the vicinity surrounding...
...cap 21 through apertures provided in the distal cap itself and/or through apertures in **catheter** shaft portion 3 proximal to distal cap 2 1. Alternatively, one or more of the **electrodes** in distal cap 49, such as **electrodes** 49, may be removed and the irrigation fluid directed through the aperture so created. Alternatively...

...is important, particularly during ablation procedures, so as to avoid overheating or charring tissue. The **catheter** of the present invention can provide for measuring the temperature of the distal cap 21 and the mapping **electrodes** at the same time. The temperature of the distal cap can then be used to provide feedback for control of ablation energy generator 13 and the temperature of the mapping **electrodes** can be monitored to be certain that the tissue that is being ablated is in...

...to one or more
thermocouples 81 (illustrated in Figure 9) may be attached to the **catheter** I for temperature sensing during ablation procedures. A temperature sensor may be in contact with...

...sensor 81 of Figure 9). hi another embodiment, temperature sensors may be disposed within mapping **electrodes** 47, 49, 5 1, for example in a hole drilled within the **electrode** . One skilled in the art will appreciate that more than one temperature sensor may be used in any particular configuration of **catheter** 1.

MethoLs ofUse
- 17 As discussed above, the **catheter** system of the invention may be used in mapping and/or ablation applications. In one...

...In the mapping application, multiple signals may be received from the heart tissue via multiple **electrodes** on the 1catheter .

Each **electrode** may measure a continuous signal (i.e., electrogram) from the heart tissue.

The continuous signal may represent the voltage of the heart tissue in contact with the **electrode** , with respect to a reference voltage, as it changes with time. The reference voltage may be obtained using a dedicated reference **electrode** or another measurement **electrode** . The quality of the signal received by each **electrode** improves as both the size 1 0 of the **electrode** and the isolation of the **electrode** increases.

Preferably, multiple **electrodes** are employed, such that multiple electrograms may be obtained simultaneously. This allows for multiple data...

...reduces the x-ray exposure to patients and physicians during fluoroscopy, when employed during the **catheter** procedure.

The mapping function of the **catheter** has a number of different applications. In one application, the **catheter** is used to measure the conductivity at various points of the septal wall, which separates...

...septal wall. In another application, the conductivity of the heart tissue is measured between adjacent **electrodes** in contact with the heart tissue to determine the continuity of a lesion formed by ablation. In still another application, the **catheter** is used to identify electrical signals within the heart that are characteristic of a number ...

...The mapping applications described above will be described in more detail in connection with various **electrode** configurations described below.

The signals measured by the **electrodes** of the **catheter** may be analyzed by the controller 9. hi one embodiment, this analysis may take place...

...may compare, add, subtract, or otherwise manipulate measured signals.

- 18 As will be described, the **catheter** can also be used for ablation procedures.

Reference is now made to Figure 13, which illustrates a method of insertion of the **catheter** 1 into a patient 31 in accordance with an embodiment of the present invention. The **catheter** 1 is inserted into the patient via a blood vessel, e.g., subclavian vein, jugular vein, or femoral vein. In Figure 13, the **catheter** I is shown entering a femoral vein 33 via an incision 35 in the thigh of the patient 3 1. The **catheter** lmay be introduced into the vein using a sheath/dilator (not shown). The sheath/dilator...

...area of incision 35. From the incision site 35 in the femoral vein 33, the **catheter** I of Figure 13 may be advanced independently, or through a sheath/dilator, up the...

...a crosssectional view of the heart taken along line A-A in Figure 13. The **catheter** 1 is shown entering the right atrium 39 via the inferior vena cava 37. For passage of the **catheter** 1 into the left atrium 4 1, the **catheter** I may be passed trans-septally through the septal wall 45. In one method, a puncture 43 in the septal wall 45 is made at the **foramen ovale** , an area of the septal wall having a decreased thickness and decreased conductivity relative to other areas of the septal wall. As described previously, in one embodiment of the invention, **electrodes** on **catheter** 1 are used to locate the **foramen ovale** , or another preferred site to puncture the septal wall. As shown in Figure 14, the **catheter** 1 traverses the septal wall 45 from the right atrium 3 9 and enters the left atrium 4 1. The **catheter** 1 may be used for mapping and/or ablation procedures in the left atrium 41...

...the pulmonary vein(s) for mapping and/or ablation. It should be appreciated that the **catheter** may also be used to perform mapping and/or ablation in the right heart, in...

...other area of the heart or blood vessels of the circulatory system, and that the **catheter** 1 need not pass through the septal wall to enter these areas.

One advantage of using a **catheter** according to the invention in the described method is that only a single **catheter** is necessary to (1) determine the location of the **foramen ovale** for passage through the septal wall, (2) perform any desired mapping procedures, and (3) perform any desired ablation procedures. This avoids the need for changing **catheters** during procedures as between, for example, mapping and ablation - 19 procedures. It may also reduce...

...needed during a patient's electrophysiology study and treatment procedure.

The various configurations of the **catheter** illustrated in the figures are exemplary.

One skilled in the art will appreciate that the number, size, orientation, and configuration of the mapping **electrodes** and the ablation **electrodes** , as well as various diameters and lengths of the **catheter** can be provided depending upon the particular application.

Having thus described at least one illustrative...

Claim
- 20
CLAIMS

1 A **catheter** , comprising:
a metallic cap including a plurality of apertures; and
at least one **electrode** disposed in each aperture of the plurality of apertures.

2 The **catheter** of claim 1, wherein the **electrodes** are insulated from the cap.

3 The **catheter** of any of claims 1-2, wherein the **electrodes** extend beyond a surface of the cap.

4 The **catheter** of any of claims 1-3, wherein the **electrodes** are mushroomshaped.

5 The **catheter** of any of claims 1-4, wherein the **electrodes** are dome-shaped.
6 The **catheter** of any of claims 1-5, wherein the cap is gold.

7 The **catheter** of any of claims 1-5, wherein the cap is platinum.

8 The **catheter** of any of claims 1-7, further comprising:
means for steering a distal end of the **catheter** .

9 The **catheter** of claim 8, wherein the means for steering includes means for steering a distal end of the **catheter** in at least one plane.

10 The **catheter** of any of claims 1-9, wherein:
the metallic cap may be used to perfonn ablation; and
the at least one **electrode** disposed in each aperture may be used to perforrn mapping. I 1. The **catheter** of claim I 0, wherein the metallic cap is constructed and arranged to optimize ablation procedures and wherein a configuration of **electrodes** is selected to optimize mapping procedures.

12 The **catheter** of claim any of claims I -I 1, wherein a surface area of the metallic cap is larger than a surface area of the at least one **electrode** .
13 A **catheter** , comprising:
a substantially cylindrical cap portion;
1 0 a substantially dome-shaped cap portion disposed distal to the substantially
cylindrical cap portion; and
first and second **electrodes** mounted to the substantially dome-shaped cap portion, but not to the substantially cylindrical cap portion.

14 The **catheter** of claim 16, wherein:
the **catheter** has an axis that extends longitudinally along a length of the **catheter** ;
and
the first and second **electrodes** are mounted at an angle of approximately 450 with respect to the axis.

15 The **catheter** of any of claims 13-14, wherein:
the first and second **electrodes** have a diameter that is approximately at or between 0.5 mm and 1.5 mm.

16 The **catheter** of any of claims 13-15, wherein:
the first and second **electrodes** are separated by a distance of approximately I MM.
17 The **catheter** of any of claims 13-16, further comprising:

a band-shaped **electrode** mounted to the cylindrical cap portion.

18 The **catheter** of any of claims 13-17, flirther comprising:
- 22 an **electrode** coupled to a source of **RF** energy and mounted to the cylindrical cap portion.

19 The **catheter** of any of claims 13-18, further comprising:
a reference **electrode** mounted to the cylindrical cap portion.

20 The **catheter** of any of claims 13-19, wherein the **catheter** has an axis that extends longitudinally along a length of the **catheter** , further comprising: at least one group of **electrodes** mounted to the cylindrical cap portion in a plane normal to the axis.

21 The **catheter** of claim 20, wherein **electrodes** of the at least one group of **electrodes** are equidistant from each other.

22 The **catheter** of any of claims 20-21, wherein **electrodes** of the at least one group of **electrodes** have a diameter that is at or between 0.5 mm and 1.5 mm.
23 The **catheter** of any of claims 20-22, wherein each group of the at least one group of **electrodes** includes four **electrodes** .

24 The **catheter** of any of claims 20-23, wherein there are four groups of
electrodes .

25 The **catheter** of any of claims 13-24' wherein the **catheter** has an axis that extends longitudinally along a length of the **catheter** , farther comprising: a plurality of **electrodes** mounted along a line that is parallel to the axis.

26 The **catheter** of claim 25, wherein each **electrode** of the plurality of **electrodes** is equidistant from each adjacent **electrode** .

27 The **catheter** of clain-i 26, wherein each **electrode** of the plurality of **electrodes** is separated from each adjacent **electrode** by approximately 1 mm. @23

28 The **catheter** of any of claims 25-27, wherein each **electrode** of the plurality of **electrodes** has a diameter that is approximately at or between 0.5 inin and 1.5 Inin.
29 The **catheter** of any of claims 25-28, wherein the plurality of **electrodes** includes four **electrodes** .

30 The **catheter** of any of claims 1-29, further comprising:
a localization sensor for identifying a location of the **catheter** .
3 1. The **catheter** of any of claims 1-30, further comprising:
a temperature sensor for sensing temperature in a vicinity of the **catheter** .

32 The **catheter** of any of claims 1-12, further comprising:
a temperature sensor for sensing temperature in a vicinity of the metallic cap.

33 The **catheter** of claim 1-3 1, further comprising:
means for irrigating in a vicinity of the **catheter** .

34 The **catheter** of any of claims 1-12 and 32, further comprising:

a temperature sensor for sensing...

...35 A method for treating a condition of a heart, comprising acts of placing a **catheter** inside the heart;
mapping a region of the heart, using mapping **electrodes** on the **catheter** ; and ablating, using an ablation **electrode** disposed about the mapping **electrodes** of the **catheter** .

36 The method of claim 35, wherein the acts of mapping and ablating are performed...45, fin-ther comprising an act of sensing temperature in a vicinity of the ablation. **electrode** .

47 The method of any of claims 35-46, flirther comprising an act of irrigating in a vicinity of the ablation **electrode** .

48 The method of any of claims 37-47, wherein the act of placing includes placing the **catheter** in the left side of the heart.

49 The method of claim 48, wherein the act of placing the **catheter** in the left side of the heart includ es inserting the **catheter** through a hole in the septum of the heart.

50 The method of any of claims 48-49, wherein the act of placing the **catheter** in the left side of the heart includes inserting the **catheter** into the heart via a femoral vein. 5 1. A method of creating a lesion in heart tissue and determining a continuity of the lesion, comprising acts of. providing a **catheter** having at least one ablation **electrode** and a plurality of
mapping **electrodes** ;
placing the plurality of **electrodes** in contact with the heart tissue at the location
of the lesion;
creating a lesion in the heart tissue using the at least one ablation **electrode** ;
detecting a signal from each of the plurality of **electrodes** ;
determining, based on the signal from each of the plurality of **electrodes** , whether
a signal exists between any adjacent **electrodes** ; and
assessing the continuity of the lesion.

52 The method of claim 5 1, wherein the act of detecting a signal from each of the plurality of **electrodes** includes simultaneously detecting a signal from each of the plurality of **electrodes** .

53 The method of any of claims 51-52, wherein the acts of creating a...

...35-45 and 48-55, ftirther comprising an act of determining a location of the **catheter** in a patient.
57 The method of any of claims 35-45 and 48-46, further comprising an act of sensing temperature in a vicinity of the **catheter** .

58 The **catheter** of claim 57, further comprising an act of sensing temperature in a vicinity of the at least one ablation **electrode** .

59 The method of any of claims 35-45 and 48-57, farther comprising an act of irrigating in a vicinity of the **catheter** .

60 The **catheter** of claim 59, further comprising an act of sensing temperature in a vicinity of the at least one ablation **electrode** .

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A CATHETER FOR CAUSING THERMAL TRAUMA TO A PATENT FORAMEN OVALE AND METHOD OF USING THE CATHETER

CATHETER PERMETTANT DE PROVOQUER UN TRAUMATISME THERMIQUE DANS UN FORAMEN OVALE PERMEABLE ET PROCEDE D'UTILISATION DE CE CATHETER

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Detailed Description
Claims

French Abstract

...puis retiree du corps du patient. La zone traumatisee creee sur les surfaces internes du **foramen ovale** permeable guerit avec le temps et se transforme en une cicatrice fermant le **foramen ovale** .

Detailed Description

A **CATHETER** FOR CAUSING THERMAL TRAUMA TO A **PATENT** FORAMEN **OVALE** AND METHOD OF USING THE **CATHETER**
FIELD OF THE INVENTION
The present invention is related generally to medical/surgical devices that...

...procedure. More specifically, the present invention is a minimally invasive device useful in closing a **patent** foramen **ovale** .

BACKGROUND OF THE INVENTION
The fetal circulation is vastly different than the normal adult circulation...

...into the left atrium through a specialized curtain like opening in the heart called the **foramen ovale** . The blood -Ifrom the left atrium then enters the left ventricle and then into the...

...The small amount of blood entering the right atrium that does not pass through the **foramen ovale** , most of which comes from the superior vena cava, flows into the right ventricle and...The decrease in pressure in the right atrium causes the curtain like opening of the **foramen ovale** to close, driving more blood into the right ventricle and then to the lungs for oxygenation. Over time, the **foramen ovale** is replaced with a membrane called the fossa ovalis. Similarly, the decrease in pressure in...

...treated or surgically ligated to close the ductus. In about one of four people, the **foramen ovale** does not seal shut, instead it remains patent. Since the pressure in the left atrium...

...adults with strokes of unknown origin (cryptogenic strokes) have about twice the normal rate of **patent** foramen **ovales** than the normal population. Although there is a correlation between strokes and **patent** foramen **ovales** , it is currently unknown why this correlation exists. Many people theorize that blood clots and...

...where it is trapped and usually cause no harm to the patient. Patients with a **patent** foramen **ovale** , however, have a potential opening that the clots or plaque can pass through the venous...

...a stroke and the associated neurological deficits.

Currently, the method of choice to close a **patent** foramen **ovale** is open heart surgery and ligation of the **foramen ovale** to ...the usually risks of general anesthesia, open heart procedures, infections, etc.

Another method is a **catheter** based method which places to opposing umbrella shaped devices around the **foramen ovale** , one in the right atrium and one in the left atrium. Unfortunately, this procedure is...

...cause thromboembolic events. What is needed therefore is a least invasive method for closing a **patent** foramen **ovale** which does not have the associated risk of an open heart procedure, is technically easy ...

...SUMMARY OF THE INVENTION

The present invention provides a device and method for closing a **patent** foramen **ovale** . The present invention comprises a **catheter** sheath with proximal and distal ends. A **catheter** is deployably retained within the **catheter** sheath. An **electrode** is provide at the distal end of the **catheter** such that adjacent tissue can be heated using **radio frequency** (" **RF** ") energy. Once the **catheter** sheath is placed by a treating health care professional across a patent foramen **ovale** , the **catheter** is advanced such that the **electrode** is deployed outside of the distal end of the **catheter** sheath. The **catheter** sheath is then removed from the foramen **ovale** and **RF** energy is applied to the **electrode** to heat adjacent tissue that causes thermal trauma to the lining of the **foramen ovale** . The **catheter** is then repositioned into the distal end of the **catheter** sheath and then removed from the patient. The traumatized area created along the inner surfaces of the **patent** foramen **ovale** heals over time and turns into a scar obliterating the **foramen ovale** .

BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements ...

...of the fetal circulation of a mammal;
Fig. 2 is a schematic diagram of a **catheter** of the present invention traveling up the inferior vena cava of a patient into the right atrium and through the **foramen ovale** ;
Fig. 3 is a schematic plan view of a **foramen ovale catheter** of the present invention;
Fig. 4 is an axial cross-sectional view of the distal end of the **catheter** of Fig.

Fig. 5 is a perpendicular cross-sectional view of the **catheter** of Fig. 3 taken along the plane indicated in Fig. 4 by line 5-5...EMBODIMENTS
The present invention provides a novel least invasive device and method for closing a **patent** foramen **ovale** in a mammal. The device is specifically designed to be used in **catheterization** laboratories in hospitals for treating humans as well as veterinary hospitals for treating animals. As...

...illustrated in Fig. 2, the device is introduced into the blood stream using well known **catheterization** procedures.

The device is initially introduced within a **catheter** sheath I I with a distal. end 14.

The device then extends distally from the **catheter** sheath to span the patent **foramen ovale** . The device has an **RF electrode** 26 at the distal end. **RF** energy is applied to the adjacent tissue using the electrode to thermally traumatize the interior tissue of the foramen **ovale** . After heat has been applied for sufficient amount of time the device is removed from the patient. Once the interior of the **foramen ovale** has been traumatized, the body's healing mechanism begins. Because the pressure within the left...

...greater than the pressure in the right atrium, the curtains of tissue that comprises the **patent** foramen **ovale** are directly opposed to each other. The body's healing mechanism then replaces the traumatized...

...scar tissue and the scar tissue forms across the curtain of tissue permanently sealing the **foramen ovale** .

Over time, the **foramen ovale** becomes completely obliterated and turns into the normal fossa. ovalis.

Turning now to Fig. 3, the **foramen ovale catheter** of the present invention is further illustrated. In order to obtain access to the blood stream, the **foramen ovale catheter** has to be advanced through the skin of the patient into a blood vessel, preferably a standard femoral vein **catheterization** is used that is well known in the art, however other vessel access to the...

...standard introducer is used to gain access from the skin of the patient to the **lumen** of the vessel. These introducers are commercially available from many different manufacturers, Cordis Corporation of...

...introducer. The introducers usually have a hollow shaft 12, a tapered distal end 13, a **catheter** access port 16 with an internal seal (not illustrated) to ensure that fluids do not...

...the introducer and to inject anticoagulant or other medications directly into the vessel.

A sheath **catheter** I 1 is then advanced through the **catheter** port of the
introducer. The **catheter** has a proximal end 12 and a distal end 14. Provided at the proximal end is a port access 13 which allows the **electrode** **catheter** to be introduced through the sheath **catheter** . The outer diameter of the sheath **catheter** can vary from about 5 French to about 15 French. The inner diameter is such that a 4 French to about a 14 French **foramen** **ovale** **catheter** can be placed within its **lumen** . In the preferred embodiment, the sheath **catheter** is a single **lumen** **catheter** made by extruding standard **catheter** materials using standard extrusion techniques. Currently it is preferred to extrude polyether-block-amide, nylon, polyurethane, polyimide, or a polyolefin copolyester. However, any other extrudable **catheter** material well known in the art can be used to manufacture the **catheter** . The smaller the **catheter** , the stronger the extruding material should be. With very small **catheters** , the **catheter** can be reenforced by using braided meshing, a technique already well known in the **catheter** arts. The sheath **catheter** 's length is such that it can easily be used from a femoral site to...

...140 cm, with about 120 . cm being preferred. Optionally, the distal end of the sheath **catheter** can have a radio
opaque marker 24 such as a metallic ring placed around the...

...the distal end is visible under imaging techniques such as fluoroscopy.

Inserted inside the sheath **catheter** 's **lumen** is a **foramen** **ovale** **electrode**
catheter 16 of the present invention. The **foramen** **ovale** **electrode** **catheter** can be made by extruding standard **catheter** materials using standard extrusion techniques, just like the sheath **catheter** . The **catheter** has a proximal end 18 provided with a standard "Y" fitting 19 and a distal...

...coil and has a blunt distal end 32 to prevent damage to vessels when the **catheter** is advanced. The angled stem 20 of the Y fitting is provided with a lure...

...standard cable 30 with optional connectors is also provided at the proximal end of the **electrode** **catheter** . The cables are connected to a supply 31 of RF energy.

Located at the distal end of the foramen **ovale** **electrode** **catheter** is the
electrode 26. Referring now to Figs. 3-5, the **foramen** **ovale** **catheter** can be comprised of two **catheters** , the outer **catheter** 16 which is placed within the **catheter** sheath, and an inner **catheter** 25 which has a **lumen** 40 for the guide wire 23.

Between the outer and inner **catheter** is an area 36 for fluid to communicate with the fluid port and the distal end 17 of the outer **catheter** and the distal end 24 of the inner **catheter** .

The inner and outer **catheters** are manufactured using well known materials and well known extrusion techniques. The outer **catheter** typically has an outer diameter of about 6 French to about 14 French,

with 8 French being presently preferred. Between the outer and inner **catheter** is an area 36 for fluid to pass through the **catheter** . The inner **catheter** is sized to fit within the outer **catheter** leaving adequate room for the fluid space 36.
An **RF** **electrode** 26 is bonded to the outer circumference of the outer **catheter** near its distal end. The **electrode** can be made out of any standard biocompatible **electrode** material well known in the art. Presently platinum or platinum alloys are preferred, however steel **electrodes** could also be used. A lead wire 46 that spans the length of the **catheter** from the Y fitting to the **electrode** is threaded between the outer and inner **catheters** in the space 36. A hole 33 is created in the outer **catheter** and the lead wire is threaded through the hole and welded to the **electrode** . During the manufacturing process, the lead wire is threaded through the outer **catheter** first and then welded to the **electrode** . The **electrode** is then placed over the distal end of the outer **catheter** and the slack on the lead wire is taken up by pulling on its proximal end. The **electrode** is then bonded to the outer **catheter** by wicking in an appropriate adhesive.

Optionally located on the inner surface of the **electrode** on the opposite side from the lead wire is a standard means 48 for monitoring the temperature of the **electrode** . Presently a standard thermocouple made out of copper and constantan wire is used. The temperature...

...to the Y fitting. The monitoring means is placed on the inner surface of the **electrode** by making a hole 34 in the outer **catheter** . The monitoring means is then bonded to the inner surface of the **electrode** prior to the **electrode** being placed over the distal end of the outer **catheter** . The **catheter** could optionally be provided with a plurality of thermocouple leads.

The **RF** energy used is typical **RF** energy ranging from about 100 kHz to about 1000 kHz, with about 460 kHz being...

...a range of about 3 watts to 2 5 watts being presently preferred. Many different **RF** generators can be used to supply the **RF** energy. Presently, an **RF** generator manufactured by Stellartech Research Corporation of Mountain View, CA is preferred. The **RF** generator can deliver a maximum wattage of **RF** energy, with that maximum wattage chosen by the user of
the generator. The **RF** generator then can measure the temperature at a thermocouple inside the needle to then regulate...degrees centigrade is used with a temperature of 85 degrees centigrade being presently preferred. The **RF** energy can be delivered for a set time ranging from I second to 500 seconds with 30 seconds being presently preferred.

Connected to the **RF** supply is a standard reference **electrode** (not illustrated) that is also connected to the skin of the patient. The **RF** energy being supplied to the **electrode** 26 of the **electrode** **catheter** is unipolar current. The reference **electrode** is used to complete the circuit from the **electrode** **catheter** to the **RF** supply.

Turning now to Fig. 6, a preferred Y type fitting 19 is illustrated. The proximal end of the outer **catheter** 16 is bonded in the distal end 53 of the Y fitting
with bonding material 52. The proximal end of the inner **catheter** extends
proximally past the fluid port 20 and is bonded in the middle of the...

...fitting with bonding material 5 1. Thus, as can be appreciated by the drawing, the **lumen** 5 8 of the fluid port is in direct communication with the fluid space 36 between the inner and outer **catheters** . The guide wire port 57 at the most proximal end of the Y fitting is...

...until the inner diameter 55 is about identical to the inner diameter of the inner **catheter** . The tapering makes it easy to place the guide wire through the **lumen** 40 of the inner **catheter** . The cable 30 is connected to the Y fitting opposite the Y arm 20. The...

...wires traverse through the Y fitting and into the space between the inner and outer **catheters** .

Figs. 7 and 8 illustrate a further embodiment of the present invention. A sheath **catheter** 61 with a distal end 63 is illustrated in cross-section. Within the **lumen** of the sheath **catheter** is a **foramen ovale** **catheter** 67. In this embodiment the foramen ovale catheter is a single **lumen** **catheter** that has a paddle **electrode** 68 attached at its distal end. The paddle **electrode** has a relatively flat profile with a thickness of about 0.050 inches. The width of the paddle is sized such that if fits within the sheath **catheter** and is wider than the diameter of the foramen **ovale** **catheter** . The paddle **electrode** has a stem 69 for insertion and bonding to the interior of the **foramen** **ovale** **catheter** . A lead wire (not illustrated) spans the length of the **foramen** **ovale** **catheter** within the **lumen** of the **catheter** from the proximal end to the **electrode** . Optionally, a means from monitoring temperature 72 is bonded to the bottom surface of the **electrode** . Presently a thermocouple is used with copper and constantan wires 7 1.

Fig. 9 is...

...embodiment of Fig. 7 however utilizing bipolar energy to thermally traumatize the tissue touching the **electrodes** . In this embodiment, the paddle 80 is actually an insulator such as nylon or a polyester. Attached the paddle are two different **electrodes** 81 and 82, one for the positive **electrode** and one for the negative **electrode** . The **electrodes** can be metal **electrode** bonded to the paddle. Currently it is preferred that the **electrodes** are manufactured by ion implanting or sputtering silver, gold, or platinum on the surface of the paddle covering the two different edges where the **electrodes** are located. Separate lead wires 83 and 84 are attached to each **electrode** . Bipolar energy can then be applied to the tissue in contact with the **electrodes** to heat the tissue. The bipolar energy will tend to stay on the surface of the tissue instead of penetrating the tissue like unipolar energy. Obviously, with using the bipolar **electrodes** there is no need for using a reference **electrode** attached to the skin of the patient.

Fig. IO is an alternate embodiment of the...

...invention similar to the embodiment of Fig. 3 utilizing bipolar energy. In this embodiment the **electrode** comprises insulators 96 separating alternating positive **electrodes** 97 and negative **electrodes** 98. The insulator would not conduct **RF** energy. The **electrodes** could be ion implanted, sputtered, bonded, or otherwise attached to the insulating material that creates the insulators 96. Preferably the **electrode** is manufactured by using a polyester cylinder and ion implanting silver, gold, or platinum. Each positive and negative **electrodes** would have separate lead wires connecting them to the supply of **RF** energy.

Those acquainted with medical procedures will appreciate that any medical procedure involving the heart...

...provides for a method of training a person to perform the procedure of traumatizing a **patent** foramen **ovale** using the disclosed embodiments. The method of training includes the steps of demonstrating the -IOdevice ...

...used similarly. First,
access is gained to a blood vessel. Typically the femoral vein is **catheterized** using any one of may commercially available introducing **catheters** that are well known in the art. Once the introducing **catheter** is in place, a single **lumen** sheath **catheter** that is long enough to reach the **foramen** **ovale** and is large enough to allow the particular embodiment of the present invention to pass through the **lumen** is placed through the introducing **catheter** . An example of this type of **catheter** is the 8 French Mullins Introducer Set manufactured by Cook of Bloomington IN. Typically these **catheters** are provided with a fairly stiff guide wire to allow for probing the right atrium for the **foramen** **ovale** . The single **lumen** **catheter** is advanced to the right atrium and then through the **foramen** **ovale** to the left atrium.

Next the guide wire is removed and the **foramen** **ovale** **catheter** is advanced in the single **lumen** **catheter** to the left atrium. The single **lumen** **catheter** is then removed from the left atrium and the foramen ovale.

The electrode is then placed within the foramen ovale and **RF** energy is applied to heat the adjacent tissue. The energy is applied for a sufficient time to cause thermal damage to the interior of the **foramen** **ovale** , currently a temperature of 85 degrees centigrade is reached for 30 seconds. The RF energy is then stopped.

The foramen **ovale** **catheter** is then withdrawn into the single **lumen** **catheter** and then removed from the patient. All the **catheters** are then removed and the puncture site is sealed using standard techniques.

The trauma created within the **foramen** **ovale** starts a healing process which over time seals the **foramen** **ovale** shut with scar tissue. Once the **foramen** **ovale** is shut, the patient no longer has the risks associated with an **patent** foramen **ovale** .

While several particular embodiments of the invention have been illustrated and described, it will be...

Claim

I A radio frequency catheter device for thermally traumatizing a patent **foramen** **ovale** comprising:

A a sheath **catheter** with proximal and distal ends;

B a **foramen** **ovale** **catheter** deployably retained within the sheath **catheter** , the foramen ovale catheter having proximal and distal ends;

C at least one radio frequency electrode attached to the foramen **ovale** **catheter** at its distal end;

D a supply of **radio** **frequency** energy attached to the **electrode** .

2 The **catheter** device of claim I wherein the **electrode** is attached to the outer circumference of the **catheter** . 3 . The **catheter** device of claim I wherein the **electrode** is attached to the distal end of the **catheter** ..

4 The **catheter** device of claim I wherein the **electrode** protrudes from the distal end of the **catheter** .

5 The **catheter** device of claim I wherein the **electrode** is shaped like a paddle.
6 The **catheter** device of claim I wherein a plurality of **electrodes** are attached to the distal end and at least one **electrode** is a negative **electrode** and a different **electrode** is a positive **electrode** ..

7 The **catheter** device of claim 1 further comprising means for monitoring the temperature of tissue that comes into contact with the **electrode** .

8 The **catheter** device of claim 7 wherein the monitoring means is a thermocouple attached to the **electrode** . . A method of thennally traumatizing a patent **foramen** **ovale** comprising the steps ofA inserting an introducer **catheter** into a vessel of a patient with a **patent**
foramen **ovale** ;
B inserting a **foramen** **ovale** **catheter** with proximal and distal ends and
with at least one **electrode** attached to or near the distal end through the introducer **catheter** ;
C advancing the foramen ovale catheter through the patent foramen ovale;
D applying radio frequency energy to the electrode to thermally traumatize the interior of the **patent** foramen **ovale** ;
E removing the **foramen** **ovale** **catheter** and the introducer **catheter** from
the patient.

10 The method of thermally traumatizing a **patent** foramen **ovale** of claim 9
further comprising the step of inserting a sheath **catheter** through the introducer **catheter** .

11 A method of training a person to perform the method of thermally traumatizing a **patent** foramen **ovale** comprising the steps of demonstrating or instructing the performance of the method of claim 9...

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00487518 **Image available**
A BALLOON CATHETER FOR CAUSING THERMAL TRAUMA TO A PATENT FORAMEN OVALE AND METHOD OF USING THE BALLOON CATHETER
CATHETER A BALLONNET DESTINE A PROVOQUER UN TRAUMA THERMIQUE DANS UN FORAMEN OVALE PERMEABLE ET PROCEDE D'UTILISATION DUDIT CATHETER
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  Detailed Description
  Claims

Detailed Description
... blood into the right ventricle and then to the lungs for oxygenation. Over time, the **foramen ovale** is replaced with a membrane called the fossa ovalis. Similarly, the decrease in pressure in...

...treated or surgically ligated to close the ductus. In about one of four people, the **foramen ovale** does not seal shut, instead it remains patent. Since the pressure in the left atrium...
...adults with strokes of unknown origin (cryptogenic strokes) have about twice the normal rate of **patent** foramen **ovales** than the non-nal population. Although there is a correlation between strokes and **patent** foramen **ovales** , it is currently unknown why this correlation exists. Many people theorize that blood clots and...

...where it is trapped and usually cause no harm to the patient. Patients with a **patent** foramen **ovale** , however, have a potential opening that the clots or plaque can pass through the venous...

...a stroke and the associated neurological deficits.

Currently, the method of choice to close a **patent** foramen **ovale** is open heart surgery and ligation of the **foramen ovale** to close it.

This obviously is associated with the usually risks of general anesthesia, open heart procedures, infections, etc.

Another method is a **catheter** based method which places to opposing umbrella shaped devices around the **foramen ovale** , one in the right atrium and one in the left atrium. Unfortunately, this procedure is...

...cause thromboembolic events. What is needed therefore is a least invasive method for closing a **patent** foramen **ovale** which does not have the associated risk of an open heart procedure, is technically easy ...

...SUMMARY OF THE INVENTION
The present invention provides a device and method for closing a **patent** foramen **ovale** . The present invention comprises a **catheter** sheath with proximal and distal ends. A balloon **catheter** is deployably retained within the **catheter** sheath.

The fluid in the balloon is can be heated using **radio frequency** (" **RF** ") energy via two **electrodes** contained within the balloon's **lumen** . Once the **catheter** sheath is placed by a treating health care professional across a **patent** foramen **ovale** , the balloon **catheter** is advanced such that the balloon is deployed outside of the distal end of the **catheter** sheath. The **catheter** sheath is then removed from the **foramen ovale** and the balloon is inflated within the foramen ovale. The treating healthcare professional then applies **RF** energy to the fluid in the balloon to heat the balloon to a temperature that causes thermal trauma to the lining of the **foramen ovale** . The balloon **catheter** is then deflated and then repositioned into the distal end of the **catheter** sheath and then removed from the patient. The traumatized area created along the inner surfaces of the **patent** foramen **ovale** heals over time and turns into a scar obliterating the **foramen ovale** .

BRIEF DESCRIPTION OF THE DRAWINGS
As used herein, like reference numerals will designate similar elements ...

...of the fetal circulation of a mammal;
Fig. 2 is a schematic diagram of a **catheter** of the present invention traveling up the inferior vena cava of a patient into the right atrium and through the **foramen ovale** ;
Fig. 3 is a schematic plan view of a balloon **foramen ovale catheter** of the present invention;
Fig. 4 is an axial cross-sectional view of the distal end of the **catheter** of Fig. 3;
Fig. 5 is a perpendicular cross-sectional view of the **catheter** of Fig. 3 taken along the plane indicated in Fig. 4 by line 5-5...
...EMBODIMENTS
The present invention provides a novel least invasive device and method for closing a **patent** foramen **ovale** in a mammal. The device is specifically designed to be used in **catheterization** laboratories ... illustrated in Fig. 2, the device is introduced into the blood stream using well known **catheterization** procedures.

The device is initially introduced within a **catheter** sheath I I with a distal end 14.

The device then extends distally from the **catheter** sheath to span the patent **foramen ovale** . The device has an inflatable balloon 26 with **RF electrodes** within the **lumen** of the balloon. The balloon is inflated while in the foramen ovale and **RF** energy is applied to thermally traumatize the interior tissue of the **foramen ovale** . After heat has been applied for sufficient amount of time, the balloon is deflated and the device is retracted into the **catheter** sheath. The device is then removed from the patient.

Once the interior of the **foramen ovale** has been traumatized, the body's healing mechanism begins. Because the pressure within the left...
...greater than the pressure in the right atrium, the curtains of tissue that comprises the **patent** foramen **ovale** are directly opposed to each other. The body's healing mechanism then replaces the traumatized...

...scar tissue and the scar tissue forms across the curtain of tissue permanently sealing the **foramen ovale** . Over time, the **foramen ovale** becomes completely obliterated and turns into the normal fossa ovalis.

Turning now to Fig. 3, the **foramen ovale catheter** of the present invention is further illustrated. In order to obtain access to the blood stream, the patent foramen **catheter** has to be advanced through the skin of the patient into a blood vessel, preferably a standard femoral vein **catheterization** is used that is well known in the art, however other vessel access to the...

...standard introducer is used to gain access from the skin of the patient to the **lumen** of the
vessel. These introducers are commercially available from many different manufacturers, Cordis Corporation of...

...introducer. Presently it is preferred to use a 7 or 8 French introducer. A sheath **catheter** I 1 is then advanced through the **catheter** port of the
introducer. The outer diameter of the sheath **catheter** can vary from about 5 French to about 15 French. The inner diameter is such that a 4 French to about a 14 French **foramen ovale catheter** can be placed within its **lumen** . In the preferred embodiment, the sheath **catheter** is a single **lumen catheter** made by extruding standard **catheter** materials using standard extrusion techniques. Currently it is preferred to extrude polyether-block-amide, nylon, polyurethane, polyimide, or a polyolefin copolyester.

However, any other extrudable **catheter** material well known in the art can be used to manufacture the **catheter** . The smaller the **catheter** , the stronger the extruding material should be. With very small **catheters** , the **catheter** can be reenforced by using braided meshing, a technique already well known in the **catheter** arts. The **catheter** has a proximal end 12 and a distal end 14. Provided at the proximal end is a port access 13 which allows the balloon **catheter** to be introduced through the sheath **catheter** . The sheath **catheter** 's length is such that it can easily be used from a femoral site to...

...140 cm, with about 120 . cm being preferred. Optionally, the distal end of the sheath **catheter** can have a radio
opaque marker 24 such as a metallic ring placed around the...

...the distal end is visible under imaging techniques such as fluoroscopy.

Inserted inside the sheath **catheter** 's **lumen** is a **foramen ovale catheter** 16 of the present invention. The **catheter** has a proximal end 18 provided with a standard "Y" fitting 19 and a distal...

...coil and has a blunt distal end 32 to prevent damage to vessels when the **catheter** is advanced. The angled stem 20 of the Y fitting is provided with a lure...

...and deflation of the balloon. The fluid used is preferably a physiological fluid that conduct **RF** energy such as saline. A standard cable 30 with optional connectors is also provided at the proximal end of the balloon **catheter** . The cable is connected to a supply 31 of **RF** energy. A standard grounding **electrode** (not illustrated) is also connected to the **RF** supply and the skin of the patient.

Located at the distal end of the **foramen ovale** balloon **catheter** is the balloon 26. Referring now to Figs. 3-5, the **foramen ovale catheter** is actually comprised of two **catheters** , the outer **catheter** 16 which is placed within the **catheter** sheath, and an inner **catheter** 25 which has a himen 40 for the guide wire 23. The inner **catheter** is longer than the outer **catheter** , the length corresponding to the length of the balloon (about I to 2 cm) plus...

...that is bonded to the wires 31 that cover the balloon. The outer and inner **catheters** can be made by extruding standard **catheter** materials using standard extrusion techniques, just like the sheath **catheter** . The outer **catheter** typically has an outer diameter of about 6 French to about 14 French, with 8 French being presently preferred. Between the outer and inner **catheter** is an area 36 ...fluid to communicate with the fluid port and the interior of the balloon. The inner **catheter** is sized to fit within the outer **catheter** leaving adequate room for the fluid space 36.

Currently the inner **catheter** has an outer diameter of about 3 French to about 12 French with 6 French...

...presently preferred. The balloon 26 is bonded to the distal end 17 of the outer **catheter** with an appropriate adhesive 39 such as heat curable polyurethane and the like. The balloon is also bonded near the distal end 24 of the inner **catheter** using an adhesive 37. This creates the fluid cavity 38 of the balloon.

The balloon...

...mm, with a diameter of 5 mm being presently preferred.

Located within the balloon's **lumen** 38 are two **electrodes** bonded to the inner **catheter** . The proximal **electrode** 42 is bonded near the proximal end of the balloon, and the distal **electrode** 41 is bonded near the distal end of the balloon. Lead wires 46 and 47 are provided for the **electrodes** between the inner and outer **catheters** . The lead wires span from the cable at the proximal end to the **electrodes** at the distal end.

Means for measuring the temperature within the balloon is optionally provided...

...using standard copper and constantan wires 48. The thermocouple is ideally bonded to the inner **catheter** at the midpoint of the balloon.

The **RF** energy is typical **RF** energy ranging from about I 00 kHz to about
1 000 kHz, with about 460...

...a range of about 3 watts to 2 5 watts being presently preferred. Many different **RF** generators can be used to supply the **RF** energy. Presently, an **RF** generator manufactured by Stellartech Research Corporation of Mountain View, CA is preferred. The **RF** generator can deliver a maximum wattage of **RF** energy, with that maximum wattage chosen by the user of
the generator. The **RF** generator then can measure the temperature at a thermocouple inside the needle to then regulate...

...degrees centigrade is used with a temperature of 85 degrees centigrade being presently preferred. The **RF** energy can be delivered for a set time ranging from I second to 500 seconds...6, a preferred Y type fitting 19 is illustrated. The
proximal end of the outer **catheter** 16 is bonded in the distal end 53 of the Y fitting
with bonding material 52. The proximal end of the inner **catheter** extends
proximally past the fluid port 20 and is bonded in the middle of the...

...fitting with bonding material 5 1. Thus, as can be appreciated by the drawing, the **lumen** 58 of the fluid port is in direct communication with the fluid space 36 between the inner and outer **catheters** . The guide wire port 57 at the most proximal end of the Y fitting is...

...until the inner diameter 55 is about identical to the inner diameter of the inner **catheter** . The tapering makes it easy to place the guide wire through the **lumen** 40 of the inner **catheter** . The cable 30 is connected to the Y fitting opposite the Y arm 20. The...

...wires traverse through the Y fitting and into the space between the inner and outer **catheters** .

Those acquainted with medical procedures will appreciate that any medical procedure involving the heart should...

...provides for a method of training a person to perform the procedure of traumatizing a **patent** foramen **ovale** using the disclosed embodiments. The method of training includes the steps of demonstrating the device...

...of the present invention are all used similarly. Fist the shape and size of the **foramen** **ovale** is detennined using standard imaging techniques such as magnetic resonance imaging, trans-esophageal echocardiography, and...

...is determined, an appropriate sized balloon can be used to fill the inside of the **patent** foramen **ovale** . Then, access is gained to a blood vessel. Typically the femoral vein is **catheterized** using any one of may commercially available introducing **catheters** that are well known in the art. Once the introducing **catheter** is in place, a single **lumen** **catheter** that is long enough to reach the **foramen** **ovale** and is large enough to allow the particular embodiment of the present invention to pass through the **lumen** is placed through the introducing **catheter** . An example of this type of **catheter** is the 8 French Mullins Introducer Set manufactured by Cook of Bloomington IN. Typically these **catheters** are provided with a fairly stiff guide wire to allow for probing the right atrium for the **foramen** **ovale** . The single **lumen** **catheter** is advanced to the right atrium and then through the **foramen** **ovale** to the left atrium.

Next the guide wire is removed and the **foramen** **ovale** **catheter** is advanced in the single **lumen** **catheter** to the left atrium. The single **lumen** **catheter** is then removed from the left atrium and the **foramen** **ovale** .
The balloon **catheter** is then placed within the **foramen** **ovale** by slowly
withdrawing the **catheter** back from the left atrium towards the right atrium. The balloon is then positioned within the foramen ovale. Once in position, the balloon is inflated and **RF** energy is applied to raise the temperature within the balloon to the desired temperature, with...

...is applied for a sufficient time to cause thermal damage to the interior of the **foramen** **ovale** , currently for 30 seconds. The balloon is then deflated and the **foramen** **ovale** **catheter** is withdrawn into the single **lumen** **catheter** and then removed from the patient. All the **catheters** are then removed and the puncture site is sealed using standard techniques.

The trauma created within the **foramen** **ovale** starts a healing process which over time seals the **foramen** **ovale** shut with sear tissue. Once the **foramen** **ovale** is shut, the patient no longer has the risks associated with an **patent** foramen **ovale** .

While several particular embodiments of the invention have been illustrated and described, it will be...

Claim
I An radio frequency balloon catheter device for thermally traumatizing a patent **foramen** **ovale** comprising:
A a sheath **catheter** with proximal and distal ends;
B a **foramen** **ovale** balloon **catheter** deployably retained within the sheath **catheter** , the **foramen** **ovale** **catheter** having proximal and distal
ends;
C an inflatable balloon attached near the distal end of the foramen ovale balloon **catheter** ;
D At least two **radio** **frequency** **electrodes** attached to the **foramen** **ovale**
catheter within the balloon;
E means for inflating the balloon with a fluid; and
F a supply of **radio** **frequency** energy attached to the **electrodes** whereby
applying **radio** **frequency** energy to the **electrodes** heats the fluid within the balloon when the balloon is inflated.

2 The **catheter** device of claim 1 wherein the **foramen** **ovale** balloon **catheter** comprises an outer **catheter** and an inner **catheter** . 3 . The **catheter** device of claim 2 wherein the inner **catheter** is longer than the outer **catheter** .

4 The **catheter** device of claim 3 wherein the balloon, outer **catheter** , and inner **catheter** all have proximal and distal ends and wherein the proximal end of the balloon is attached to the distal end of the outer **catheter** and wherein the distal end of the balloon is attached to the inner **catheter** .

5 . The **catheter** device of claim I wherein there are two **radio frequency electrodes** , the first one is located within the balloon near the balloon's proximal end and...

...second one is located within the balloon near the balloon's distal end.

6 The **catheter** device of claim 1 further comprising a Y fitting attached to the proximal end of the **foramen ovale** balloon **catheter** .

7 The **catheter** device of claim 6 further comprising a cable connecting the **radio frequency** supply to the Y fitting.
8 The **catheter** device of claim I further comprising means for monitoring the temperature within the balloon.

9 The **catheter** device of claim 8 wherein the temperature monitoring means comprises a thermocouple attached to the **foramen ovale** balloon **catheter** at its distal end within the balloon.

10 A method of therinally traumatizing a **patent** foramen **ovale** comprising the steps ofA inserting an introducer **catheter** into a vessel of a patient with a **patent**
foramen **ovale** ;
B inserting a **foramen ovale** balloon **catheter** with proximal and distal
ends and a balloon attached near its distal end and with at least two electrodes attached to the foramen **ovale catheter** within the balloon;
C advancing the **foramen ovale** balloon **catheter** through the patent foramen **ovale** ;
D inflating the balloon with a **radio frequency** energy conducting fluid;
E applying **radio frequency** energy for a sufficient time to the **electrodes**
to thereby heat the fluid within the balloon and to thereby thermally traumatize the adjacent tissue of the **patent** foramen **ovale** ;
F deflating the balloon; and
G removing the **foramen ovale catheter** and the introducer **catheter** from
the patient. . The method of thermally traumatizing a **patent** foramen **ovale** of claim 1 0
further comprising the step of inserting a sheath **catheter** through the introducer **catheter** .

12 A method of training a person to perform the method of thermally traumatizing a **patent** foramen **ovale** comprising the steps of demonstrating or instructing the perfon-nance of the method of claim...